Design of a 3D printed surgical guide to assist bone graft surgical interventions

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Abstract

3D printing seems to be the tool that will lead personalize medicine in the near future; combined with the potential of medical imaging, now it is possible to use the images of each patient to create 3D specific printed devices that fit perfectly with their anatomy; On the field of trauma and orthopedics, many 3D printed surgical guides are already being commercialized to assist any sort of bone surgeries [1].

However, one of the procedures which still does not have instrumentation support is the harvesting of allografts. Allografts are pieces of bones that are used to be implanted on bone defect lesions with the purpose of recovering its initial anatomy. The graft must be harvested before being implanted to match with the shape of the lesion; this process is still done manually by surgeons so a helper guide to assist the harvesting process would be convenient.

In this thesis, I established a protocol for the design of a graft assisted guide in the form of a program that makes the process easier and automatic. The design of the guide was done for a particular case of a patient suffering of anterior shoulder instability. Several guides were designed and 3D printed to be tasted on an in vitro environment. The guides showed perfect fit on the graft and the program reduced the time that was taken to create the guides.

Further tests must be performed to ensure the reliability of the guide and some improvements on the software should be performed as well.

Keyboards: 3D printed surgical guides, allograft, shoulder instability.
1. INTRODUCTION

1.1 BONE LOSS AND BONE GRAFTING

Bone loss occurs when there is an unbalance between the bone that is formed and the bone that is reabsorbed. There are many causes that lead to bone loss; they can be traumatic, degenerative conditions or chronic instability. In all cases, Surgeons’ challenge is to restore the previous anatomy. Different techniques were described to heal bone loss, among them, the one that is normally carried is bone grafting.

Bone grafting consists in implanting a piece of bone at the point of the bone defect, this piece of bone is taken either from the same patient or from an external source and it is called graft. What happens during bone graft transplantation is that the cells of the surrounding bones repopulate making the natural bone replace the graft as the fracture heals over a period of time. This process is made possible thanks to the biological mechanisms of osteoconduction, osteoinduction and osteogenesis [2,3].

- Osteoconduction occurs when osteoblasts detect a framework where they can populate and grow through. [4]. The bone graft is placed as a scaffold close to the bone while osteoblasts spread on the scaffold and generate new bone.

- Osteoinduction is the process where bone stem cells differentiate to osteoblasts to create more bone. This mechanism speeds up the process of bone formation

- Osteogenesis occurs when the osteoblast from the graft itself can produce more bone growth despite the other two mechanisms.

Grafts can be classified according to where they are obtained: They can be autologous (or autogenous); which means they are harvested from the patient’s own body (normally from the iliac crest), allograft; where the bone is taken from a bone bank, or synthetic, which refers to grafts that are made of biocompatible
materials that mimics the mechanical proprieties of the bone. Normally the most used are autologous grafts and allografts.

The primary advantage of using an autologous graft as opposed to an allograft is that due to the presence of living cells, they can induce the growth of neighbor bones and merge with them very fast. This is possible because they can induce osteoinduction and osteogenesis processes. However, the problem with autografts is that they are harvested from the patient’s body so surgeons need to do a second incision to harvest the graft. This can lead to complications as well as an increase of morbidity [5,6].

Normally an allograft is preferred if the patient is not very old and the region of the bone defect has plenty of living cells so the graft can be perfectly populated. However, if the patient is old and the surrounding area of bone defect is poor of cells, it is better to use an autograft to ensure that the graft will perfectly merge with the surrounding bones.

1.1.1 Allografts

Allografts are taken from cadavers whose bodies have been donated for the purpose of extracting their bones to help others; normally this task is carried out by a bone bank, an external company that takes the bodies and extract the bones from them. Next, the bones undergo a long sterilization process that kills all the cells therefore making the bone a graft. The graft may come from different bones and in different sizes, depending on the needs of the surgical intervention, surgeons chose the most adequate one. Normally most of the grafts come from the tibia pilon, femoral head or proximal tibia and its cost oscillates around 400€ [7].

Allografts are not implanted directly; they are normally much bigger than the size of the lesion so before their implantation, surgeon harvest the graft to ensure that fits on place. It is important to note that the graft is harvested without any reference; the only thing surgeons know is the size the graft piece should have
and the shape of the surrounding bones where it will be implanted. The process of harvesting is normally done by trial and error; they carry out an initial harvesting and if it does not fit to the lesion they keep reshaping it until it does. This procedure is not very accurate as the final shape of the harvested graft will not perfectly fit with the bones that are part of the lesion.

Clinicians of the Department of Trauma and orthopedic surgery (TOC) from Hospital Tauli, and in particular, MD. Ferran Fillat, came with a novel solution that could fix those problems. The idea consists on designing a cutting guide that sticks on the graft and has a set of orifices that helps surgeons to harvest through them. The helper guide must be designed using two sets of medical images: Those from the fractured bone, and those from the graft that will be used. The primary objective is to plan the way the graft must be harvested so as the resulting piece harvested through the guide fits perfectly to the lesion and has the most adequate shape.

In Hospital Taulí about two hundred allografts are requested per year from the TOC, on almost all the bone defects problems, allografts can be used if the lesion is severe [8]; In some of those interventions the graft is inserted on the middle of a big fractured bone with the purpose of filling it, on those cases, the shape of the transplanted graft is not relevant. However, in most of bone grafting interventions the shape of the harvested piece of bone is very important because the purpose of the graft is to fulfill the initial shape of the bone. On those cases, the use of a helper to harvest the graft would be very convenient because it will ensure that the harvested piece of graft completely recovers the initial anatomy of the bone defect.

1.1.2 Bone harvesting

As the guide will assist the harvesting by the use of surgical instrumentation, it is important to describe them as well as the role they play on the harvesting process.

Among all the tools that are used in a trauma intervention, three of them are commonly used for cutting bones: The most used and practical one is the surgical saw (Figure 1); The tool consists of a handle that subjects the main body where
A cutting saw is located in one extreme. The saw has a square shape that vibrates across a small angle. Normally the tool is powered by high pressure air as the force that is needed to cut the bone is significantly high. Although it is one of the most used tools to cut bones, the shape of the blade limits the orifices where the saw could cut; As the blade has a rectangular shape it works very well if the guide orifice is just a flat line. However, if the orifice presents an irregular shape then the blade may not be able to fit on the orifice across the whole cut.

Surgical drill is also commonly used: It has the same main structure as the surgical saw but instead of having a blade it contains a rotating drum where different needles can be attached (Figure 1). It is mainly used to drill holes on the bones prior to insert the screws, however, it can also be used to mark the bone, and then, ending the harvesting by following the holes by the saw. The main design of the guide will be based on that way of harvesting.

Finally, chisels with different sizes are also very common. As they are smaller compared to the other mentioned tools, it is the most suitable tool when surgeons need to harvest a bone that is in a place where the access is difficult.
Figure 1 Top left: Surgical drill and saw from the company “deSouther Medical” (Source: http://www.desouther.com). Top right: Cutting blades recharges for the surgical saw (Source: Hospital Parc Taulí). Bottom left: A pair of chisels with different diameters (Source: Hospital Parc Taulí). Bottom right: Needles used by the surgical drill to mark the bones (Source: Hospital Parc Taulí).

1.2 PATIENT SPECIFIC GUIDES

Is it important to have a flat view about the patient specific instrumentation that is currently used to guide any sort of bone harvesting. They will serve as the starting point for the design of the guide.

The two most common procedures where patient specific guides are used are in shoulder arthroplasty and knee arthroplasty, where the articulation bones are harvested in a very specific way to align the prosthesis [9]. As small errors on the alignment of the prosthetic components can lead to the failure of the prosthesis, is it crucial to make the cuts as accurate as possible; That is the main reason why patient specific cutting guides play an important role on these procedures [1].
Those guides present an ergonomic structure that fits perfectly on the articulation, they present some orifices that are used to attach the guide to the surrounding bones for keeping it on place. Finally, it contains several cutting blocks that will guide specific surgical instrumentation to perform incisions into the bones for aligning the prosthesis later on.

The same technology is used to treat severe scoliosis patients. Some companies are starting to commercialize specific surgical templates that serves as a guide for clinicians to correct the curvature of the spine.

It is important to mention that even though there is no product currently on the market to assist the harvesting of allografts, one patent is currently active that describes a surgical instrument to improve the current technic of allograft bone harvesting [10, 11]. The tool is not intended to be patient specific but they provide some adjustable cutting blocks to help the process of harvesting the graft.

1.3 BIОCOMPATIBILITY OF THE MATERIAL

One of the most important points that must be covered is the biocompatibility of the material that would be used to print the guide. Even though the guide does not have to be in contact with the patient, it is mandatory to sterilize it. Another important point that has to be considered is the possibility to deposit particles of the guide’s material on the graft when this is harvested. If the material is toxic for the body the particles would cause a toxic reaction on the body once the graft is implanted.

Among the three main 3D printing manufacturing technics, Selective Laser Sintering (SLS) is the most suitable for the medical sector for its resolution and range of materials.

As all 3D printing methods, SLS is an additive manufacturing process which means that is based on the addition of layers to create the model. In SLS, a very thin layer of powder (down to 10 microns) is placed on the bottom of the printer base; then a high-power laser draws a pattern melting the powder where the laser
irradiate it, a roller adds another thin layer of powder and the laser draws another coat. This process is repeated until all the layers are finished.

Here, Polyamide 2200 (PA2200) was selected as the material for several reasons; First one, PA2200 is a Nylon polymer that meets all the criteria of the USP-Biological Test Class VI/121° as well as the corresponding ISO 10993 standards. This certifies that the material is suitable for short term implant on a human being. Secondly, its melting point is between 172 – 180 °C, enough to resist the autoclave sterilization process where 134 °C is the maximum temperature that is reached. This is important because autoclave is the standard sterilization procedure that is carried in the hospitals.

Several surgical patient-specific guides are already on the market and they are manufactured with PA2200. Materialize and smith&nephew are two examples of companies that commercialize this kind of guides. In Catalonia, the company AVINENT, which is also collaborating with the TOC, also makes 3D printed patient-specific guides.

As the guide must not be in contact with the patient, the possibility of printing it using FDM technology was also explored initially. Several have been already performed to see weather common FDM materials such as PLA or ABS would be able to be sterilized [12, 13]. Among them, PLA seems to be the good candidate because is a biodegradable material and its toxicity levels are very low [14].

However, sterilization with autoclave does not work on those materials because they deform at very low temperatures [15]. Nonetheless, sterilization technics such as ethylene oxide have showed that PLA printed parts can be perfectly sterilized without altering the chemical and mechanical proprieties of the printed part [16].

1.4 BANKART LESION / GLENOID BONE LOSS

One example of bone defect where this concept of guide could have a very significant impact is on glenoid defects. Glenoid is a part of the shoulder located on the lateral angle of the scapula, its main function is to articulate the humerus. When there is a significant bone loos on the glenoid, the articulation could not
hold the humerus anymore and the patient suffers a shoulder dislocation. If the bone loss is very severe the dislocations can happen repeatedly becoming a chronic problem, it receives the name of bony-bankart lesion.

1.4.1 Bristow-Latarjet procedure

The intervention that is normally performed to fix a bony-bankart lesion is a Bristow-Laterjet procedure [17], which is a bone grafting intervention. It consists on transferring the coracoid (it is the autograft) with its attached muscles to the defect of the glenoid (Figure 2). Even though the procedure is very well known and widely used, up to 30% of the interventions have complications and the rate of recurrent luxation after the procedure is still high (from 3% to 5%) [18,19]. It is described than when the glenoid defect is higher than 20 %, an allograft transplantation should be carried [20,21]. Using allograft transplantation has shown better results than a bristow-latarjet procedure [22,23].

Figure 2 Scheme of the bristow-latarjet technique. A: Sagittal view showing the glenoid bone defect. The inferior surface of the coracoid is highlighted in blue. B: After harvesting the coracoids the graft is rotated 90 degrees and the is attached on the lesion of the glenoid. The graft is fixed with two screws on the glenoid. C: Axial view that shows how the graft is placed so as it maintains the articular curvature arc of the glenoid. H: Humerus, G: Glenoid cavity [17, 18]

A patient suffering from shoulder instability with a severe glenoid defect was currently being treated by clinicians from the TOC, the patient had to be operated in June 2017 so it was decided to perform an allograft transplantation. Glenoid
has a very rounded surface that is crucial to be aligned with the head of the humerus. The goal of its reconstruction via a graft transplantation is to ensure that its final shape is as similar as possible as a healthy one. This makes the design of the proposed guide suitable for treating this case thus the objectives of the project are going to be centered on that particular clinical case.

1.4.2 Patient clinical history

The patient is a 29 years old male, he is a chef by profession and frequently does mountain sports. Ten years ago, he had a traumatic luxation due to impact after falling off. Since then he has had different episodes of recurrent luxation on the right shoulder. An articular test balance is performed and it shows that he had a 160° of flexion, 43° of external rotation and L3 of internal rotation.

He has signs of anteroinferior luxation and on an artro-MRI he is diagnosed of a bankart lesion / anterior glenoid lesion which is generally referred to as shoulder instability. A CT scan is requested and it shows that he has a 50% deficiency of glenoid surface (Figure 3). A graft implant is recommended.
1.5 SPECIFIC OBJECTIVES

The work consists of creating a protocol to design a cutting guide that will be attached on the bone graft and will facilitate the harvesting process. The guide is designed using the medical images of the fractured bone and of the graft being used, so that the piece of bone resulting from the harvest fits perfectly on the fractured bone. The guide system design also has to accomplish the following points:

1. The design process must be semi automatized so the clinicians can design the guide by themselves for different patients.

2. To harvest the graft, specific clinical instrumentation would be used so the guide must assist the harvesting process by being able to be worked on with those tools.

3. The guide must be perfectly affixed to the graft so it does not move when surgeons harvest through it.

There is also a need to prove that the design works. A test to check its functionality will also be performed. The resulting designs will be printed and the graft as well to perform simple fitting tests.

The above can be summarized into two specific objectives for the thesis:

1. To Implement a software tool and methodology for designing guides for facilitating bone harvesting

2. To demonstrate the software tool and the methodology by designing and 3D printing a guide to be used in an in vitro test.
2. METHODS

Even though the ways the guide could be designed are endless, the main pipeline of the design process was clear: I was required to design a system with two inputs: The medical images of the fracture and the graft, and one output: A 3d model of the cutting guide (Figure 3). The process had to be integrated on the same program and some of the steps had to be carried out by the clinicians.

Even though the use of the system design can be extended to any pair of fractured bone and graft, the design process will be centered on the patient described on the previous section. The target bone to restore will be the glenoid and the Tibia pilon will be used as the allograft (Figure 5).

2.1 SYSTEM DESIGN

From the medical images to the final 3D model of the guide, there are 4 main steps that need to be accomplished:

1. Segmentation of the images: The bone geometries from the DICOM images coming from the CT of the patient need to be extracted to assist the whole design of the guide.

2. Estimation of the missing part: Once the 3D models are obtained, the next step is to estimate the geometry that will fulfill the lesion. It is important to note that this part must be done by the clinicians because they are the ones that know how the lesion should look like after the graft is implanted.

3. Decide from which part of the graft the missing geometry will be harvested.

4. Once we know the place where the graft must be harvested the last step is to create the cutting blocks that will form the guide.
2.1.1 **Segmentation of the medical images**

Segmentation is one of the most straight forward steps; It basically consists on selecting from the medical images the geometry of interest. Two segmentations had to be performed: A segmentation of the glenoid cavity from a shoulder CT and one from the graft.

To perform the segmentation 3D slicer was used, an open source program that is used for 3D visualization and processing of medical images. 3D slicer is a modular software where their operations are packed in small modules. To perform the segmentation 3 steps are needed: (The whole segmentation protocol is shown in Annex 1)

1. Transform the 2D slices of the CT images to a 3D model.
2. Crop the volume to select the region where the glenoid cavity is contained
3. Perform the segmentation by applying a threshold where the brightest pixels (bone) are kept.

![3D Slicer Segmentation Module](image)

*Figure 4 Screenshot of the 3D slicer segmentation module. On the top there is the 3D model that has been generated from the segmentation. On the bottom there are the 3 views of the CT, axial, sagittal and coronal from left to right.*

The result of the segmentation of the glenoid can be seen on Figure 4. As the glenoid cavity is a region of the scapula, the remaining 3D model of the segmentation contains the whole bone as well as the clavicula. As for the design of the guide the glenoid cavity is the only geometry need it, the region needs to be isolated from the rest of the scapula. This operation was done by *Meshmixer*, a free modeling software used to postprocess 3D models. This software was also used to perform the whole design of the guide.
After the segmentation and the postprocessing of the segmented images is done, we end up with both 3D models, the tibia pilon (used as a graft) and the glenoid (the fractured bone) (Figure 5).

![Figure 5 3D models generated after the segmentation and postprocessing, on the left the glenoid cavity of the lesion and on the right the tibia pilon.]

2.1.2 Alignment of the models

The next step consists on estimating the remaining piece that will be produced from the harvesting of the graft. The graft being used on that intervention has been selected so that its anatomical properties are analogous to the ones of the glenoid; The top surface of the pilon has a slight curvature on the edges that can be used to match the curvature of the glenoid called glenoid arc (Figure 5).

If the implant piece is harvested from the lateral part of the pilon, two cuts on the pilon will be enough to create a geometry that not only fits to the lesion but also maintain the curvature of the glenoid arc (Figure 6). By using this approach, the two following processes (estimating the missing part, and selecting it from the graft) can be achieved with a simple alignment of the two 3D models.
One important note is that this step must be performed by clinicians because they know how the repaired glenoid should look like after the graft is implanted. The process of alignment is done by moving and rotating the 3D models until clinicians are satisfied with the result. Even though everything is done qualitatively without any sort of technical help, the goal is to ensure that the remaining articular glenoid arc between the defective glenoid and the pilon is as similar as possible as the one of a healthy glenoid. Once the alignment process is done, the setup for creating the guide is ready.
2.1.3 Design of the guide

The two previous steps are very straightforward; segmentation can be done in less than 5 minutes and with some practice, the alignment can be also done in a moment. For that reason I have not cared too much about the automatization of those processes, however, the design of the 3D model of the guide is much more complex. Depending on the way the guide is designed, the software and modeling tools that will be needed may differ a lot.

2.1.3.1 Meshmixer

The task of choosing the best software to create the design was probably the hardest and most time-consuming step of the thesis. One of the main criterion was that the software must have the ability to be programed, so I had to be able to create a sort of script that would control the operations of the 3D modeling software. After trying and using lot of programs I ended up using the one I was expecting the least, Meshmixer.

Meshmixer is a free software from the company Autodesk, a very well-known company for their software products on CAD design. Even though the software is intended to be used to postprocess models before being 3D printed, It possesses very powerful meshing tools that make it a good candidate to deal with the postprocessing of 3D models segmented from medical images [24].

There are two reasons I ended up using it: The first one was because it was simple, and the second because it has an API that allowed me to automatize some of its functionalities [25]. It is important to notice that even though the source code of the API was launched on 2014, there is neither examples nor tutorials online. This made the use of the software quite challenging.

Meshmixer (mm) API contains a set of functions and applications written on C++ that can be used to run mm operations. It also contains a linking code that allows it to connect with other programming languages. In my case, all the main code was written on python but as the software is still on development some basic c++ functions were also build.
2.1.3.2 Structure of the design program

The program I build is structured in different scripts, each script contains a set of functions and operations that performs a precise step of the design. Once the script is opened, a terminal window pops up and tells the instructions to the user. Once the block is done, it turns off and the next script starts. The code was also uploaded on github to serve as a tutorial for other people: https://github.com/jpuig005/AllograftHarvestingGuide

As mentioned early, the guide has been designed to assist two cuts; one from the top and one from the lateral (Figure 6). The guide will assist the insertion of a set of needles (Figure 1) that will make a chain of holes on the graft. Then, the guide will be removed and the surgeon will perform the final harvest with a surgical saw following the holes done by the needles. This approach was used to avoid the deposition of any particles from the material’s guide to the surface of the pilon.

Other approaches will be discussed later but they all share the same design principles.

The program is divided into four steps: 1. Alignment and duplicating the models 2. Design of the lateral cut 3. Design of the upper cut 4. Join bridge and fixers

The first step (Alignment) is already described before but as the guide is mainly designed from the meshes of the pilon and the glenoid, the 3D models must be duplicated and renamed to proceed to the following steps.

2.1.3.3 Alignment and duplicating the models

The program automatically loads the two 3D models, they have to be inside the same folder where the code is and they have to be renamed as “Pilo.stl” and “Glenoid.stl”. Once they are loaded the rotating tool is automatically activated and the user has to manually align the two models. Once the files are aligned the user must press enter on the cmd and the program will automatically generate two copies of the Pilon and two of the glenoid (Figure 7). Then, It will hide all the objects but one glenoid to continue to the next step.
2.1.3.4 Lateral cut

Five tubes equal spaced will be placed perpendicular to the neck of the glenoid. To do so, the user will have to put manually 2 pairs of 5 3D points called pivots on the opposite lateral surfaces of the glenoid (Figure 8 A). A pivot is basically a 3D point that can be placed on a vertex, edge or face of the surface. They are useful because you can import models and align them to their normal vectors. In this specific design, pivots will serve as a guide for positioning the tubes.

Once the pivots are on place, the program will iterate over 5 times loading a 3D file of the tubes each iteration (Figure 8 B). Each tube is made of two solids; the inner tube, which is going to be used to make the holes, and the outer tube, which will become the driver of the needles. The radius of the tube can be changed by the clinician according to which needle they want to use.
Figure 8 A: Glenoid with transparency showing the 10 pivots, five on each site. The pivots have the three normal vectors represented in blue, green and red small lines. B: Tubes being aligned with each pair of pivots. C: Model of 3D file of the needle containing two solids: the innertube to make the hole (white) and the outer tube to guide the needle (gray). D: The innertube is slightly smaller than the inner ring of the outer tube, this will allow the separation of the two solids later on.

Once the tubes are aligned to the pivots, the next step can be executed. The program renames the tubes, hides the glenoid and shows a pilon. Then it automatically switches to the selecting tool where the user will have to select the surface of the pilon that will become the lateral cutting block. To transform the selected surface of the pilon to the lateral cutting block, the program will automatically perform a set of operations shown on the following figure (Figure 9).
Once the cutting block is generated the next step consists on aligning the needles with the plane across their long axis. The program iterates tube by tube and the user can relocate them to the correct place. The goal is to merge the outer tubes with the plane so as the ends of the tubes are completely inside the cutting block (Figure 10). Once they are in place, the program separates each of the five needles into two geometries; the inner tube and the outer tube. This is possible because the two tubes are not completely merged (Figure 8 D); There is a small gap between them that allows mm to use the tool called “separate shells” to disjoint the two solids.

Finally, the outer tubes are combined with the plane and the inner tubes are subtracted from the cutting block to create the holes. All these steps are done automatically.
2.1.3.5 Upper cut

The way the upper cutting block is done is mostly the same as the lateral one but with one important difference. The upper cut plane must follow the curve of the neck of the glenoid. If the resulting harvested piece does not have the same curvature, the fitting will be wrong and the resulting curvature of the glenoid arc will not be the same as the one that was established at the beginning of the design.

In this case, it is convenient that the alignment of the tubes is done as precise as possible avoiding the manual positioning of them. To do so, I implemented a very simple approach; Meshmixer pivots have three normal vectors that represents their local x, y and z coordinates (Figure 8). Hence, it is possible to align imported models to one of those vectors. By positioning the pivots such that one of its normal vectors is perpendicular to the slope of the neck of the glenoid, it is possible to make a perfect alignment (Figure 11).

As the wall of the slope is very sharp, there is the risk that the normal of the pivots are not well aligned with the slope of the neck. For that reason, a simple smooth is applied on the geometry to create a soft and uniform surface. Once this is done the pivots can be arranged uniformly on the wall and the tubes can be aligned (Figure 11).
Figure 11 Top Left: Glenoid after the smoothing process. The blue line of the pivot is the normal vector where the tube will be aligned. Notice that the vector has the same slope as the glenoid neck. Top Right: 3D model of the top guide once finished. Bottom: Upper cut tubes after the alignment process.
2.1.3.6 Join bridge and fixers

Once the cutting blocks are created the only step that remains is to join them and create two holes to fix the guide in place. Following the same surface extrusion strategy, the bridge can also be created from an extrusion of surface of the pilon. In this case the selected surface is extruded far from the pilon to avoid direct contact with it.

The only thing remaining is the holes that will keep the guide in place. As explained before, the harvested piece from the graft will be placed on the lateral part of the glenoid with two screws, so after being harvested, surgeons will have to make two holes to put the screws; It is convenient that this two holes are also done by the use of the guide.

Taking that into account, the two holding holes can be designed as they also serve to perforate the harvested piece as well. On the following picture the red lines represent the place where the needles will be inserted to fix the guide and to fix the piece of graft on the glenoid as well (Figure 12).

![Figure 12](image-url)

*Figure 12 Left: Final guide (gray) aligned with the pilon (white) and with red the place where the holding needles will be placed. Right: Glenoid with the tubes that show where the screws will be attached.*
3. RESULTS

Following the same idea, several guides were designed using the same method. The point was to create guide variants to later discuss with clinicians which one could work better. The guides have been designed using the same method described before but with the goal of being used by different tools.

The guides were 3D printed with a FDM machine, a printrbot simple metal, the 3D models of the pilon and the glenoid were printed as well to perform a fitting test.

The surface of the guide was perfectly arranged with the surface of the pilon (Figure 13). Once the guide was on place the fit was almost perfect; A simple fitting test was performed where the guide was pressed tight to the pilon to see if it could slide through it. Even though the guide could move a little bit across the lateral the fitting was very robust. This small error was probably because the guides as well as the pilon were printed with FDM technology which has a very low resolution.

![Image of guides and surface fitting](image_url)

*Figure 13 1, f: Principal design described on methods. 2, b: This guide has some rectangular holes which serve to fit a chisel. 3, c: This one is also made to fit a chisel but instead of having orifices it just has one side that is used to support the tool. 4,e: Same as the first but assisting smaller needles. a: Same as the main design but without the lateral cut. d: This was the first prototype done, it contains the holes but not the tubes to drive the needles.*
3.1 HARVESTING SIMULATION RESULTS

Once the guide was created a harvesting simulation was performed to estimate the final shape of the graft. The simulation was carried by meshmixer where different meshing tools were used to simulate the harvesting process.

Two sets of 5 cylinders were placed according to the slots of the guide, they were subtracted from the pilon to simulate the insertion of the needles. Then, using the selecting tool, the points were followed selecting the area that will be harvested. The rest of the pilon where discarded and the gaps created by the use of the previous tools were closed. Once the 3D model of the harvested piece was obtained it was fit on the glenoid.

As shown in Figure 14, the harvested piece of the pilon fits perfectly on the glenoid.

Figure 14 A: 3D model of the pilon with all the tubes where the needles will pass through. B: Pilon once harvested by the needles, the tubes have been subtracted from the pilon. C, D: Resulting fitting of the piece of pilon with the glenoid, lateral and top view respectively.
3.2 AUTOMATIZATION SPEED IMPROVEMENT RESULTS

To figure it out if the semi-automatization program improved the speed of the design process, several design processes were timed. As it takes the same time to design the lateral cutting block and the upper cutting block, just the process of designing the lateral cut was timed. The total time of the guide can be approximated to twice the one measured.

To avoid processing speed bias, two tests were performed on different times. On each test, 3 pair of designs were done with and without the assistance of the program. The results are showed on Table 1.

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<thead>
<tr>
<th>Second test</th>
<th>Manually</th>
<th>Program-assisted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7 min 48 sec</td>
<td>5 min 23 sec</td>
</tr>
<tr>
<td></td>
<td>8 min 03 sec</td>
<td>5 min 01 sec</td>
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<tr>
<td></td>
<td>8 min 26 sec</td>
<td>5 min 40 sec</td>
</tr>
</tbody>
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*Table 1 Results of the time that take to make the guide.*

In average, the lateral cutting block of the guide was designed in 7 min and 54 seconds without using the program and in 5 min and 38 sec with the assistance of it. Using the semi-automatization program, it takes 2 min and 7 seconds less.
Even though there is no significant reduction of time, it is important to notice that the program also serves as a guide for the user to perform the design. By the use of it is much easier and straightforward to make the design.

4. DISCUSSION

The feedback of the surgeons was very positive regarding the final set of designs. The design they were most satisfied was the one shown in Figure 13.2. This guide was designed to be used by a chisel; as the cutting surface of a chisel is higher than the one of a needle, it would be easier, once the cut is done, to do the final harvesting of the graft.

Even though the guide showed a potential to be used on the clinical practice, it is not clear that this sort of forming guides for allograft bone grafting could be extended to many other cases. Most of the times, the final shape of the graft is not as important as on the case that was treated on this work, that is why a further study should be done about the bone grafting interventions where the shape of the final implanted graft is relevant enough so a guide with those characteristics would present a substantial increase on the results (time of the intervention and recovery of the patient).

Nonetheless, despite the importance of the final shape of the graft, this guide permits the surgeon to make a guided harvesting of the allograft ensuring that this will at least fit into the lesion which already reduces the time of this part of the intervention.

It is important to mention that at the beginning of May, the surgeon responsible of the patient described on this thesis, decided to use an autograft instead of an allograft so the guide I designed will not be used on the intervention. However, since then, the company AVINENT has been collaborating with the TOC developing a similar guide than the presented here but for assisting the harvesting of the autograft. In this case, the surgeons decided to take the fragment of bone from the iliac crest so the guide has been designed to be
inserted from an incision done in the right down part of the belly and to fit with the external top part of the Iliac crest. Even though the design was very different, the purpose is the same, harvesting a piece of bone with a specific shape to be used as a graft. This reaffirms that this sort of cutting guides are supported by the surgeons.

5. CONCLUSIONS

At the end of the thesis a complete design process for creating a graft guide system was implemented. The process was simple but robust with the possibility of modifying it according to the needs of clinicians. The semi automatization software was implemented to assess all the design process and it significantly reduced the designing time of the guide.

Using the same design pipeline several guides were also designed and 3D printed to extend the concept of the guide to be used for other clinical instrumentation. The guides showed perfectly fit on the graft and potential to be used on the real case.

The work has established a basic design pipeline for a further development of any type of allograft bone harvesting guide.
6. BIBLIOGRAPHY


[25] Autodesk, Inc. Meshmixer API (v0.0 2016) [computer software API]. Available from [https://github.com/meshmixer/mm-api](https://github.com/meshmixer/mm-api)
7. APPENDIXES

7.1 3D SLICER SEGMENTATION PROTOCOL

Obrir Imatge DICOM

1. Anar a File -> Dicom -> Import o directament al segon icona del menú
   1. Seleccionar la carpeta que conté tots els arxius .dcm; ens apareixerà una pestanya, donar a copy files

3. A cada una de les tres vistes seleccionar el 3r arxiu: “ExtrHR 0.6 B65s” i clickar el botó de centrar situat a l’extrem esquerra de cada pestanya de vista.
Segmentació

1. Anar al mòdul de volume rendering per tal de visualitzar 3D la imatge. El mòdul es troba a Modules -> Volume Rendering.

1.1 Seleccionar l’arxiu:
1.2 Activar la casella “volume”:

1.3 Seleccionar un “preset” acord amb el tipus d’imatge, en el cas de l’os un dels dos primers. Ajustar el llindar fins que només es visualitzi os:

2. Tallar la zona d’interès. Per tal de limitar la zona de segmentació tallem un cub. Per fer això cal activar la pestanya “Display ROI” al mateix mòdul de Volume Rendering. Amb les boles de colors que apareixen podem delimitar la zona.
3. Anar al mòdul de Crop Volume, seleccionar com a input Volume la imatge que estem treballant i clickar “Crop!”
4. Editor; Amb aquest mòdul es fa la segmentació. Hi ha various maneres d’accedir al mòdul, la més fàcil ésclickant a l’Icona en forma de llapis a la part superior:

El procés de segmentació pot variar en funció del que es vol segmentar però aquests són els passos estàndards:

- Threshold

L’eina llindar et permet seleccionar de la imatge només aquelles parts que estan dins d’un determinat rang de la senyal. Els llindars d’aquests rangs es varien amb el lliscant. Una vegada fet cal clicar el botó d’apply. (Recordeu que si us equivoqueu sempre podeu tornar enrere)

- Efecte illa
Aquesta eina permet seleccionar, dels elements preseleccionats per l’eina anterior, aquells volums que estan aïllats uns amb els altres. En aquest exemple, seleccionem la vertebra d’altres elements com els vasos sanguinis o altres estructures òssies. Per fer això cal primer canviar el color, seleccionar la casella de la eina en qüestió i finalment seleccionar a qualsevol de les 3 vistes l’estructura que es desitja aïllar.

- Volume generator

Un cop tenim seleccionada la nostra estructura final només cal generar el volum. Per fer això simplement s’ha de seleccionar la casella corresponent, seleccionar el color de l’estructura que es vol generar el volum i clicar “apply”. Per accedir als volums generats (per si es volen eliminar o simplement amagar) s’ha d’anar a la casella de “Models” que es troba a la part superior de la interfície i marcar o desmarcar els icones en forma d’ull.
*Cal desactivar el volum que prèviament heu tallat per tal de que no es solapin volums. Per això s’ha d’anar a Volum rendering i deseleccionar la casella “volume”.

Guardar el stl: L’últim pas és guardar els .slt generats. Cal anar a File -> Save. En la pestanya que apareix s’ha de: 1. Deseleccionar tots els arxius generats, 2. Seleccionar el/els arxius 3D generats, 3. Canviar el format d’aquests arxius de .vtk a .stl. 4. Seleccionar la carpeta destinatària i 5. Clickar a “Save”:

Aquí es pot mirar el color dels volums que heu generat