Good practice guide for medical XCT image acquisition and analysis

Deliverable D3

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Project 15HLT09 “MetAMMI Metrology for additively manufactured medical implants”.

Due date: 31st January 2019

Submission date: 19th June 2019

metAMMI

Metrology for Additively Manufactured Medical Implants

Contents

1. Introduction

X-rays were discovered at the end of the 19^{th} century. During the next century X-ray devices and techniques were developed. Both use and interpretation two dimensional gray-scale X-ray images became routine. The next innovation with large impact was the invention of Computer Tomography (CT or XCT) in the 70's. CT makes use of computer-processed combinations of many X-ray measurements taken from different angles to produce cross-sectional (tomographic) images (virtual "slices") of specific areas of a scanned object, allowing the user to see inside the object without cutting. Therefore CT scan images provide more-detailed information than plain X-rays do.

An important step in CT is the tomographic reconstruction. The principle is shown in figure 1.

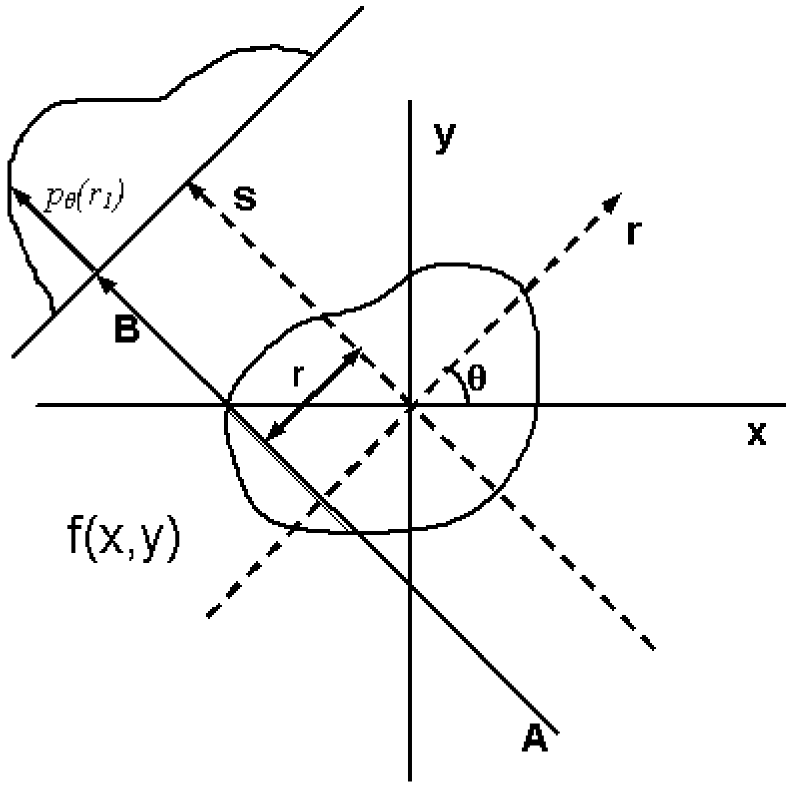

Figure 1. Parallel beam geometry utilized in tomography and tomographic reconstruction. Each projection, resulting from tomography under a specific angle, is made up of the set of line integrals through the object (picture from: https://en.wikipedia.org/wiki/Tomographic_reconstruction retrived 9.5.2019).

CT devices exist in different configurations and it is not in the scope of this guide to present these. However, as examples, a scanner is shown in figure 2 and a cone beam scanner for dental use is shown in figure 3.

Figure 2. Dual Source CT Scanner Siemens SOMATOM Definition Flash (picture from: https://www.siemens-healthineers.com/fi/computed-tomography retrieved at 9.5.2019).

Figure 3. Cone Beam CT (CBCT or DVT) scanner Planmeca ProMax 3D LE with volume 110 mm x 80 mm (picture from: https://www.planmeca.com/na/imaging/3d-imaging/3d-imaging/promax-3d-le/ retrieved at 9.5.2019).

Cone beam CT "CBCT" systems as the one shown in figure 3 are known as "DVT", also, in particular in the field of dentistry. CBCT systems differ from conventional CT systems in some relevant features:

1st CT systems detect the signal by some arrays of detectors (detector rows), while in CBCT or DVT generally the signal is collected by a flat panel image detector like in conventional radiology or fluoroscopy. This feature generally leads to the fact that CBCT systems acquire images with smaller voxel[1] sizes

2nd 3D image reconstruction as formerly presented works well in parallel or wide angle geometries. In cone beam geometries scenarios reconstructions become more difficult. Cone beam systems can suffer from limitations in resolution and distortion, particularly further from the centre part of the image.

3rd CT systems are far more complex, e.g. with respect to filtration of the beam as well as the variability of acquisition parameters. This limits the applicability of CBCT systems. Generally, CBCT systems are well suited for the inspection of high contrast structures, while they suffer from strong limitations when low contrast soft tissue structures come into play.

4th X-ray tube and detector follow a circular path around the imaged object in CT and CBCT imaging. The time to acquire an image using CT is less than a second on today's systems, while imaging with CBCT still lasts between 10 seconds and 20 seconds. This leads to the effect that CT imaging for many body parts is possible without relevant errors from patient movement, while for CBCT imaging movement errors always have to be considered. These limit the overall achievable resolution of patient images, even with much smaller resolutions technically achievable.

5th CBCT systems generally are smaller and more flexible than CT systems. These systems are therefore found typically on sites where clinicians have a need for prompt 3D imaging such as dentistry, neurosurgical or orthopaedics practices or surgery theatres.

Within CT imaging several quality parameters might be considered. In the following, we concentrate on those parameters that are of major importance for implantation processes. Parameters of lower relevance for this task, like low contrast resolution, will not be considered.

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[1] Voxel: cuboid volume element in the image

The Hounsfield Scale

After reconstruction of 3D images, there result voxels that contain a signal value. This signal value for CT systems is not an arbitrary number, but the values are given using an internationally agreed scale, the Hounsfield Scale. The unit of this scale is the Hounsfield units (HU). Values in this scale are a measure of the deviation of the electron density of the material within a voxel from the electron density of water. It is calculated as:

$$HU = 1000 \times \frac{\mu - \mu_{\text{water}}}{\mu_{\text{water}} - \mu_{\text{air}}}$$

where μ_{water} and μ_{air} are the linear attenuation coefficients of water and air respectively. Thus, the CT numbers reflect certain materials and in particular can be used to segment different parts of the body. In CBCT systems, unfortunately, the standardization is not as far evolved as in CT systems. CBCT-systems use different, sometimes proprietary, scaling systems. In some cases the same material gets a different value depending upon the overall composition of materials in the field of view.

In this guide different aspects of medical XCT, CT as well as CBCT, are covered. The data and information given in this guide are based on experiences gained in the Project 15HLT09 “MetAMMI Metrology for additively manufactured medical implants”. This project has received funding from the EMPIR programme co-financed by the Participating States and from the European Union’s Horizon 2020 research and innovation programme.

2. General considerations and image acquisition

In this chapter, we discuss general aspects of cone beam (CBCT) and conventional CT image acquisition for planning patient specific additively manufactured medical products.

2.1 Dental Cone Beam CT / Digital Volume Tomography

3D medical X-ray imaging using CT or more recently cone beam CT (CBCT) is frequently used in dental clinics and practices, e.g. for planning dental drilling guides to be used in dental implantology. For this, (CB-) CT delivers a key component: information on structure of the jaw bones, remaining teeth and location of vulnerable tissues and structures, such as nerves, near the desired implantation site. The use of X-ray imaging is the only method to assess these structures. When fused with surface scans of casts or intraoral moulds or, more conveniently, direct intraoral scans, the resulting dataset enables oral surgeons to plan their insertion with all relevant data at hand.

The X-ray dose of dental CBCT-systems strongly depends on the size of the acquired volume, which varies considerably between different vendors and models. However, dose is usually below doses for comparable studies performed in conventional CT. However, because of the large variety of CBCT systems on the market it is impossible to state exact values or to give a definitive recommendation without full knowledge of the applied protocols, systems and also patient details. Nevertheless, it should generally be kept in mind, that dental CBCT delivers best results only for high contrast objects such as bones or teeth. Imaging of soft tissues usually suffers from low contrast resolution and stronger noise compared to conventional CT. As in most cases, imaging of high contrast objects is sufficient to prepare a dental drilling guide, this does not limit the applicability of CBCT to this subject. If a visualisation of soft tissues becomes relevant, CT should be preferred.

Recommendations for acquiring dental CBCT/CT data

- Be sure to document a justifying indication for X-ray application in accordance with your local laws and medical guidelines.
- Chose the modality and protocol with appropriate image quality and lowest possible dose. Dental CBCT is preferable for computer assisted planning.
- Use a sufficiently high acceleration voltage to reduce beam hardening artefacts.
- Carefully centre the dental arch in the field of view using the laser system. This will reduce geometric distortions and improve overall geometric precision and image quality.
- Carefully set the size of the field of view (FOV). A smaller FOV increases resolution and reduces irradiated areas. However, make sure to include all relevant parts of the jaws.
- Select thinnest possible slice thickness and smallest possible slice interval for reconstruction.

- The reconstruction kernel is a set of mathematical filters being used to reconstruct axial images from the X-ray raw projection data. Since these are proprietary and vendor specific, it is hard to recommend explicit kernels. However, an acquired scan can be reconstructed again with alternative kernel and slice parameters to identify a well working set of settings. Generally, a sharp drawing kernel is preferable.
- The choice of reconstruction kernel might influence the trueness of obtained signal values. Many surface identification algorithms used for model fusion rely on certain signal value thresholds to identify model surfaces. Thus, planning suites have to figure out well working, reliable kernels for image reconstruction. Once, a well working kernel has been identified, it should not be changed to obtain constant surface reconstruction results. Be aware of probably significant measurement uncertainties of signal values. Some support to get best possible results might be provided from medical-physics experts. Get in touch with them, when possible.
- Ask the patient to remove any artificial dentition or other radio-opaque objects from the oral cavity to reduce beam hardening artefacts (when possible). Such artefacts will disturb the fusion process, so that a perfect fitting of DVT/CT and optical scan is hard to achieve, even with manual intervention.
- Ask the patient to hold absolutely steady and not to swallow at all times to reduce movement artefacts. Movement artefacts do not only influence overall image quality and degrade registration results. They may also lead to falsely planned angulations.
- Separate jaws a little bit from each other, either using facilities of the DVT-modality (if available) or by placing a slap of a radiotransparent material of some mm thickness between upper and lower incisors. This helps reducing possible artefacts from the opposite jaw and eases recognition of the dental surface.
- Follow legal regulations of general radiology concerning image archiving as well.

Further understanding of the implications of dental CBCT acquisition for AM manufacture of dental drilling guides can be found in Case Study 2 of the report: '*Demonstrating the errors related to each manufacturing step from medical imaging to patient application*' also produced by the MetAMMI project.

2.2 Conventional Computed Tomography

For planning and fabricating patient specific implants or drilling guides like cranial bone replacements or neurosurgical drilling guides, conventional computed tomography is the method of choice as it is routinely available in clinics.

Recommendations for acquiring conventional CT data

- During CT, the patient is usually exposed to a significant radiation dose. Be sure to document a justifying indication in accordance with your local laws and medical guidelines. Special care must be taken for children and pregnant women.
- Chose a protocol with appropriate image quality and lowest possible dose. In many cases, the manufacturer of the implant will provide input for designing appropriate CT protocols and reconstruction settings. As the field of possible applications and CT systems is very wide, explicit protocol designs are beyond the scope of this guideline. For further information we recommend to get in contact with the local medical physics expert in charge.
- Carefully centre the relevant anatomy in the isocentre of the gantry by employing its laser alignment system. This will not only enable the scanner to optimize radiation output but it will usually also reduce distortion and increase resolution slightly.
- Some manufacturers of implants do not accept cranial CT datasets, which were acquired with a tilted gantry as correction of such a tilt is not possible on their systems. Ask the manufacturer for details. Whenever possible try to use tilted gantries for scans of the neurocranium in order to avoid an exposure of the lens of the eye by the direct beam.
- Carefully set the size of the field of view. A smaller FOV increases resolution and reduces irradiated areas. However, make sure to include all relevant anatomies.
- Select thinnest possible slice thickness and smallest possible slice interval for reconstruction with respect to the implant's manufacturer's opportunities. The thinner the slices get the better gets the special resolution of your model. This, however, comes along with an increase of the radiation exposure to the patient.
- The reconstruction kernel is a set of mathematical filters being used to reconstruct axial images from X-ray raw projection data. Since reconstruction algorithms and kernels are proprietary and vendor specific, it is hard to recommend explicit kernels. However, an acquired scan can be reconstructed again with alternative kernel and slice parameters to identify a well working set of settings. Generally, a sharp drawing kernel is preferable.
- The choice of reconstruction kernel might influence the trueness of obtained CT numbers. Most surface identification algorithms used for model fusion rely on certain signal value thresholds to identify model surfaces. Thus, planning suites have to figure out well working, reliable kernels for image reconstruction. Once, a well working kernel has been identified, it should not be changed to obtain constant surface reconstruction results. Be aware of probably significant measurement uncertainties of signal values. Some support to get best possible results might be provided from medical-physics experts. Get in touch with them, when possible.
- Ask the patient to remove any artificial dentition or other radioopaque objects from directly irradiated areas when possible. Such objects with high Z materials will lead to beam hardening artefacts that will later disturb the planning process as surface might not be easily visible or distorted.

- Ask the patient to hold absolutely steady to reduce movement artefacts. Movement artefacts do not only influence overall image quality. They may also lead to falsely planned angulations, if relevant. Fortunately, nowadays the scan time is about one second for such restricted ranges as to be scanned for implantations.
- Follow legal regulations of general radiology concerning image archiving and reporting as well.

Further understanding of the implications of CT acquisition for AM manufacture of maxillofacial implants, pedicle screw drill guides and cranial plates can be found in Case Studies 1, 3 and 4 respectively of the report: '*Demonstrating the errors related to each manufacturing step from medical imaging to patient application*' also produced by the MetAMMI project.

3. Image quality degrading influences

Besides the general discussion of dental cone beam and conventional CT in the previous chapter, this chapter focuses on special aspects that will degrade overall image quality.

3.1 Resolution

Just like every other imaging device, medical computed tomography (CT) systems suffer from limited image resolution, which may influence a derived additively manufactured product. Since CT is a complicated technique, involving not only the acquisition but also reconstruction and post processing, many different (partly device and software specific) influences need to be considered.

As CT and CBCT systems differ in their construction, considerably, some of the following considerations are valid for one type of system, only. This will be mentioned in the following.

General considerations

- CT images are mathematical reconstructions of X-ray absorption data from different angles and for some cases at different z positions. Those absorption data are reconstructed using proprietary algorithms, which use so called "reconstruction kernels". Reconstruction kernels enable the user to put special focus on dedicated features of the dataset, as low or high resolution. In many cases as a compromise the improvement of one parameter degrades the quality of the other. Thus, reconstruction kernels have to be chosen with the dedicated clinical need in view. High end CT systems nowadays to some extend provide elaborated reconstruction approaches that are able to overcome this tradeoff. The field of CT reconstructions is by far too broad to be covered in the frame of this guideline with sufficient depth. For further information we refer to the public available literature.
  For implantation purposes one may consider, generally, that a use of "sharp" kernels is favorable over "softer" ones. As a tradeoff this increases the noise, which is no big deal for

the given task as the contrast from the bony structures to the surrounding tissue typically is sufficiently high.

- For CT systems, the selected axial field of view is projected on a fixed 512 x 512 pixel matrix. The smaller the selected axial field of view, the smaller the effective voxel size within one slice and thus, the higher the resolution.
- For CT systems, the resolution in z direction primarily depends on the selected slice thickness and the selected slice interval. The larger interval and thickness, the lower is the z-resolution. Due to increasing partial volume artefacts with thicker slices, the slice thickness may also have an influence on axial resolution.
- CT systems provide X-ray tubes with large and small foci. While the large focus yields worse resolution, its radiation output is higher. Using the smaller focus usually leads to better resolved images. However, exposure times might increase and lead at a certain point to movement errors.
- The axial resolution is usually highest at the isocentre, while it drops in more peripheral regions. In general, patients should be thoroughly centered in the isocentre with the body part, where the implantation should take place, in mind.
- If the patient moves during acquisition, movement artefacts will of course degrade image resolution. However, even if a patient rests perfectly still, organs like the heart will induce certain movements. For CT-systems patient movement is a minor problem, especially for imaging the skull. CBCT systems, however, clearly suffer from movement errors as their exposure times are more than a factor 10 above those from CT systems. Patients have to be informed asked strictly to stay still while the image is acquired.
- Manufacturers of implants provide scanning guidelines and sometimes also explicit protocols.
- Finally: All X-ray applications must be carefully indicated by adequately qualified physicians according to local radiation protection laws. Radiation dose and resulting image quality must both be considered at all times.

Further understanding of the implications of kernel and resolution choice for AM manufacture of maxillofacial and spinal implants can be found in Case Study 1 and 3 respectively of the report: '*Demonstrating the errors related to each manufacturing step from medical imaging to patient application*' also produced by the MetAMMI project.

3.2 Geometric distortion

All CT devices suffer from inherent distance measurement uncertainties due to image distortion. For some clinical tasks, this distortion can play a relevant role, especially whenever distances are measured, e.g. to estimate size or location of a structure in the body. For a precise planning of implants, geometrical accuracy is of course one of the most relevant aspects.

It assumed that the device specific scanning and reconstruction parameters have an impact on the geometrical distortion of medical systems. Therefore these influences were addressed on several CT and CBCT-systems from different manufacturers during the MetAMMI project.

Influence of multiple scanning geometric parameters such as scan mode, slice thickness, patient centering or gantry tilting as well as several X-ray and reconstruction parameters were investigated.

From the results, it was concluded that slice thickness has a significant influence on the geometrical distortion of the scan. Larger slice thicknesses presented significant more distorted results. Second, the accurate centering of the patient was found to be relevant. The other parameters tested (i.e. kernel/window, scan mode, pitch, exposure time, gantry tilt, collimation, effective mAs[2] and voltage) were found to be of minor influence on the distortion.

General recommendations

- Always demand explicit scanning instructions from your implant manufacturer. These protocols should be carefully checked for accordance to medical and radiation protection guidelines in close cooperation with your medical physics expert before implementation.
- CT-Data with the smallest possible slice thickness and distance yielded less geometric distortion.
- Generally distortions enlarge the more one comes to the edges of the field of view. Thus centering is essential for a reduction of distortion errors.

3.3 Artifacts

Image artefacts arise from a large variety of reasons – Some can be circumvented, some cannot. Some artefacts are generated because of technical issues (e.g. badly calibrated or defective detectors), some result from the patient such as beam hardening artefacts or movement artefacts and some are inherent in the technology itself such as partial volume artefacts.

Depending on the class of artefacts, the accuracy of a computed tomography for planning implants can be influenced in very different ways from slight geometric distortions to general unreadability of the desired region of interest. For example, if bone density is interpreted from measured CT-numbers, issues such as beam hardening will lead to errors.

Powerful artefact suppression technology (often based on iteratively operating reconstruction algorithms) may reduce artefacts visually. However, these techniques will alter image data in a hard to control manner, making derivation of explicit quantitative data difficult.

Since there is a huge number of different machines and reconstruction techniques available on the market and there a many different classes of artefacts, we refer to medical guidelines as well as manufacturer recommendations and largely available general scientific literature to address this issue.

General recommendations

- Avoid high z materials, like metals, in the area between X-ray source and detector. Their absorption can result in images that are of no use for the task. Thus,
    - Remove metal parts whenever possible from the body;

[2] mAs: X-ray tube current time product

  - Rethink patient and beam orientation. In some cases a change of patient position or the beam axis helps to remove metal parts from the direct beam.
- As iterative reconstructions alter signal values, check carefully the function of surface finding and segmentations algorithms for the usability in patients with high z materials.

4. Data handling

Since the obtained image data is digitally processed during the planning phase, accurate export, transmission and segmentation is crucial to extract the best possible surface for CAD of the desired implant. In this chapter, we will provide some general considerations concerning these aspects.

Advances in image processing software has made it far simpler to extract the surfaces of structures of interest from 3D medical imaging data. At present there is a wide range of well known, free and open-source image segmentation tools such as Seg3D, 3D Slicer or Osirix. While not discussed here, such tools make this process very accessible and easy to follow.

4.1 Export of image data

For planning and fabricating additively manufactured medical implants and guides, acquired image data needs to be exported from the modality or the archive and transferred to the CAD systems of the manufacturer. The best compatibility and image quality are usually achieved using the internationally established DICOM[3] standard. Furthermore, patient data and relevant technical parameters (such as for example the voxel size) are included in the DICOM metadata for each image, facilitating patient attribution and further processing.

General considerations

- Always follow the instructions of the implant/guide manufacturer and the manufacturer of your imaging modality. Specific products might need specific information and data.
- Make sure, that patients were not confused during registration at the modality, as patient data is always encoded in all images.
- In many cases, it is sufficient to provide only original axial slices with thinnest possible thickness and distance. Other reconstructions, e.g. MPR of sagittal slices only provide further redundant data. The manufacturer’s specifications should precisely define, which reconstructions shall be exported. If unsure, please ask your implant / guide manufacturer for specific details.
- Comply with legal obligations concerning personal data protection.

[3] DICOM: Digital Imaging and Communications in Medicine; worldwide agreed format for documentation, transaction and storage of radiological image data

4.2 Segmentation

The following section outlines a basic workflow that can be used to convert volumetric medical imaging data from X-Ray CT to a 3D virtual model. The process consists of three steps: image segmentation, mesh refinement and 3D modelling/printing.

Segmentation of the bone from other parts of the body can be performed by thresholding of voxel signal values. For CT systems signal values are generally measured in Hounsfield units (HU), which are mathematically based on the deviation of the electron density of a material from those of water. Bone structures show up with prominently high HU-values. A signal value of a material should stay constant for different reconstruction algorithms and kernel. However, as noted previously, is not always the case.

CBCT systems in most cases do not follow the HU-approach. The signal values of materials result from some proprietary, vendor dependent algorithms. Further, these values to some extent are influenced by the mixture of tissues in the field of view. Thus, signal values might differ from expected ones in case of patients that differ from the normal cohort.

Three methods can be used to determine the threshold value used to perform segmentation. An expert user with sufficient knowledge in the relevant anatomy and XCT image interpretation can determine manually a suitable threshold. However, this approach has low repeatability and reproducibility as the threshold is determined subjectively. A method known as 'ISO 50' is commonly used to automatically determine a suitable threshold value based on the histogram of voxel intensities. This method first determines the two peaks in the histogram that correspond to the material of interest (e.g. bone) and the background (e.g. soft tissue). The threshold value is then determined as the mean of the intensities of the material and background. However, 'ISO 50' is more suitable for single material objects where the peaks in the histogram appear relatively sharp and unskewed. In medical applications, a number of different tissues exhibiting a range of density values are present in the imaging region. As a result, the distribution of voxel intensity in the histogram becomes skewed and wider, causing inaccurate determination of the two peaks, especially the peak that represents the background (e.g. tissues surrounding the bones). Therefore, the automatically determined threshold value sometimes deviates from the optimal threshold. A more advanced method, that determines the threshold in two steps, can be used to improve upon the sub-optimal threshold. In the first step, an initial threshold is determined manually or by 'ISO 50'. In the second step, local intensity gradient in the direction normal to the material/background boundary (i.e. determined by initial threshold) is calculated for voxels that lie on the boundary. The new local thresholds are then determined at positions where maximum value in the local gradient occur. This step is then repeated iteratively, using the previously determined threshold as the initial threshold. While the first two methods use a single threshold for segmentation, the gradient-based method determines individual threshold values for each voxel. Therefore, it is able to achieve better segmentation accuracy in general. This gradient-based method is currently not yet implemented in medical segmentation software, such as Materialise Mimics.

After segmentation by thresholding, a meshing process is performed to create a 'polygonised' mesh that represents the surface of the material of interest (e.g. bones). Some post-processing tasks may be applied afterwards, such as filling of holes and smoothing filtering. Staircasing errors, which can be a direct result of the medical slice-based scanning process, can also be smoothed out. The mesh data can then be exported, typically in STL[4] format to be used in other software for design, manufacturing or analysis purpose.

General considerations

- Check the constancy and validity of signal values at least at installation and new software releases.
- Take possible deviations of signal values from the true ones into account when setting thresholds for segmentation purposes.
- In particular for CBCT systems, check the constancy and validity of signal values for different material combinations. The signal values for bone might be relevantly influenced from the presence or absence of surrounding structures.
- In case of subjective determination of thresholds check at least when setting up the process and when new team member enter the inter user variability and its consequences on the fabrication process.

[4] STL: Standardi Triangulation Language