Safety of medical operations using 3D models developed in cooperation with medical browsers and delivery of a sterile implant model to the operating room

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Abstract

Modern medicine also bases its science on the possibility of practicing skills on 3D models and 3D prints, as well as on imaging thanks to the use of virtual reality (VR). CAD software has been widely used in fields of medicine such as dentistry, surgery including orthopedics, transplantology, cardiology, rehabilitation and all other fields of medicine. Safe medical staff also means safe patients. An important issue is risk analysis, which includes activities that are part of process planning and risk management. All these activities enable the person supervising the entire process to identify, plan and manage risks in order to reduce or completely eliminate threats. The safety of both patients and medical staff is the primary goal of every medical sterilization department. This goal is achieved by controlling infections by providing sterile materials to the operating room.

(1) Background: The cooperation of medical browsers and CAD software was studied to create an anatomical model of the knee joint and then carry out the medical sterilization process as a basis for eliminating infections of medical staff and patients, which translates into the safety of medical operations.

(2) Methods: Developing a 3D model using a medical browser and CAD software, then printing a knee implant using 3D printing and carrying out the sterilization process.

(3) Results: 3D printing of the knee joint, carrying out the sterilization process and protecting medical staff and patients against biological infections.

(4) Conclusions: 3D prints of anatomical models can be easily and quickly prepared thanks to the appropriate transformation of the file from the medical browser to CAD software and then the 3D model can be printed on 3D printers. The 3D printed model allows for proper and safe preparation for medical operations, and it can also be a ready-made implant for transplantation into the patient. Thanks to the use of medical sterilization activities and procedures, the 3D implant can be a ready-made sterile material to be brought into the operating room. This protects patients and medical staff against biological infections. The safety of patients and medical staff contributes to the reduction of cross-infections caused by surgical instruments.

Key words: 3D models, implant sterilization, patient and medical staff safety, medical browsers, CAD software, 3D printing.

Introduction

A very important element of a doctor's work is the ability to view X-rays or other tests, e.g. computed tomography (MRI), ultrasound or other imaging tests. The results of imaging tests are available to doctors and patients in a digital version, on CDs or USB drives, as well as in the hospital's computer network. Thanks to this, the doctor can review imaging tests several times and perfectly prepare for the patient's treatment, as well as plan medical operations. An essential tool for a doctor is a medical browser, in other words, a program that allows you to view the patient's imaging tests. DICOM file viewers are such a solution. DICOM is an abbreviation for Digital Imaging and Communications in

Medicine. Thanks to the standardization of the data recording method, it is possible to read it by any medical equipment, including those from different manufacturers. DICOM files can be viewed using medical viewers available on the market. DICOM files can also be used for other purposes. One option is 3D visualization. A very large number of images generated during the examination allows you to create a three-dimensional 3D model, which can be saved directly from the medical browser as a sparse .stl file, i.e. a file suitable directly for 3D printing, or this three-dimensional model can be transported to CAD software into three-dimensional space and there anatomical elements that have been diseased or destroyed can be modeled and recreated in such a way that a full-fledged three-dimensional 3D implant is created, which can also be 3D printed. The visualization of the patient's body created on the basis of 3D technology also gives the possibility of manipulating the image - rotating, zooming in, zooming out, modifying the contrast and exposing the most important layers. Due to these properties, visualizations are increasingly being talked about as an opportunity to perform even more precise surgical procedures. The article was written thanks to the medical cooperation of Artur Harmata, MD, from the ORTOVITA Hospital in Rzeszów, Podkarpackie Province, and Aneta Myszka, MD, from the Department of Neurosurgery at the 10th Military Clinical Hospital in Bydgoszcz, Kujawsko-Pomorskie Province, who prepare for the treatment and surgery of patients thanks to 3D technology and the possibility of 3D printing. A CT scan was performed on the patient to determine an accurate assessment of the morphology of the knee joint fracture with the need for 3D reconstruction on the patient. For this purpose, a medical viewer of DICOM files was used as shown in the following images:

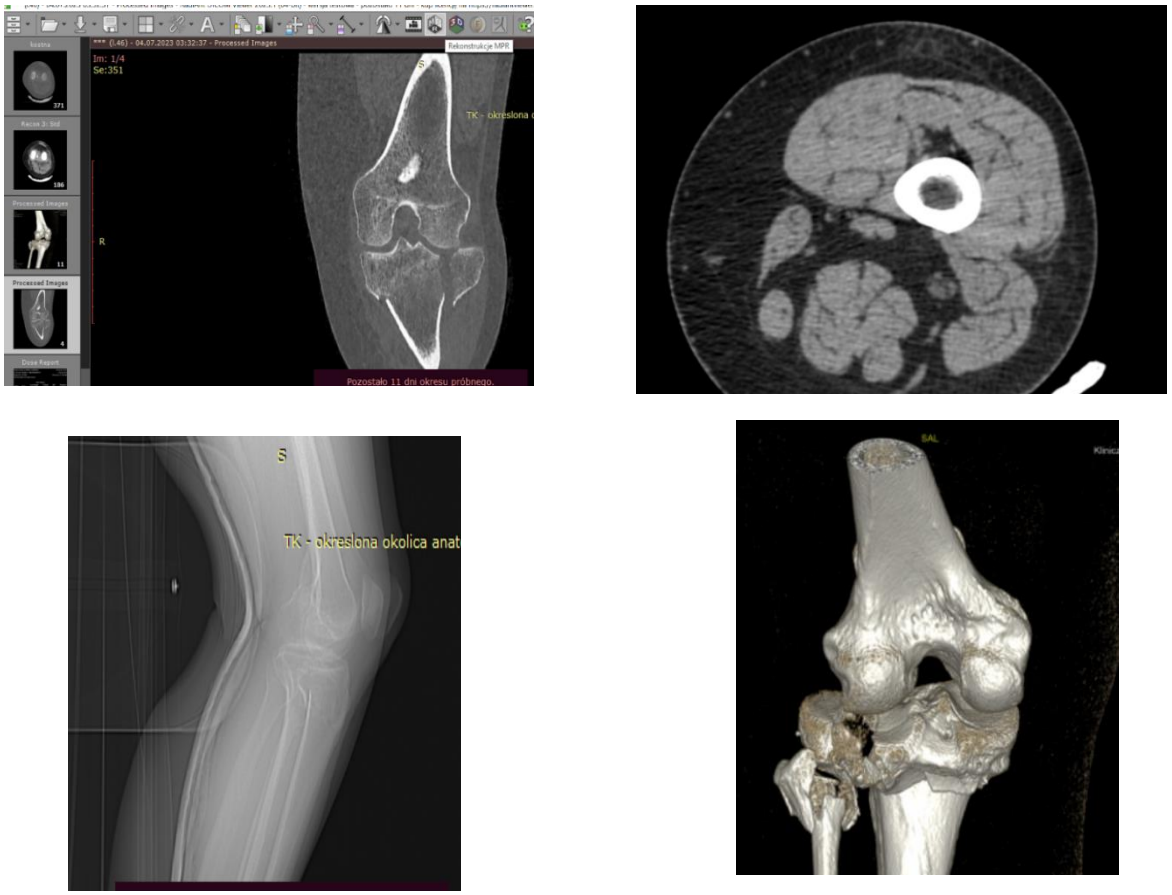
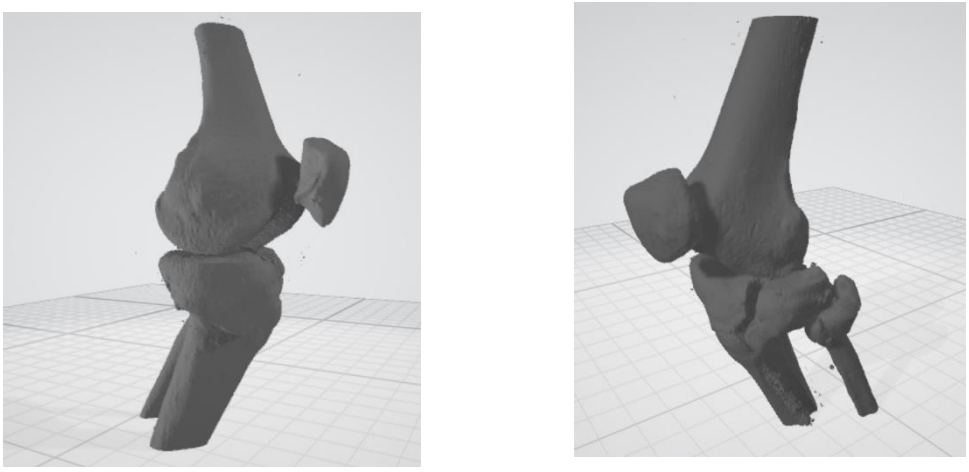


Photo 1, 2, 3, 4. Imaging a patient's medical examination in a medical browser – DICOM files

The patient's medical examination, which is visible in photos 1, 2, 3, 4, was performed using a computed tomography scanner for the left ankle joint. The examination was performed in spiral

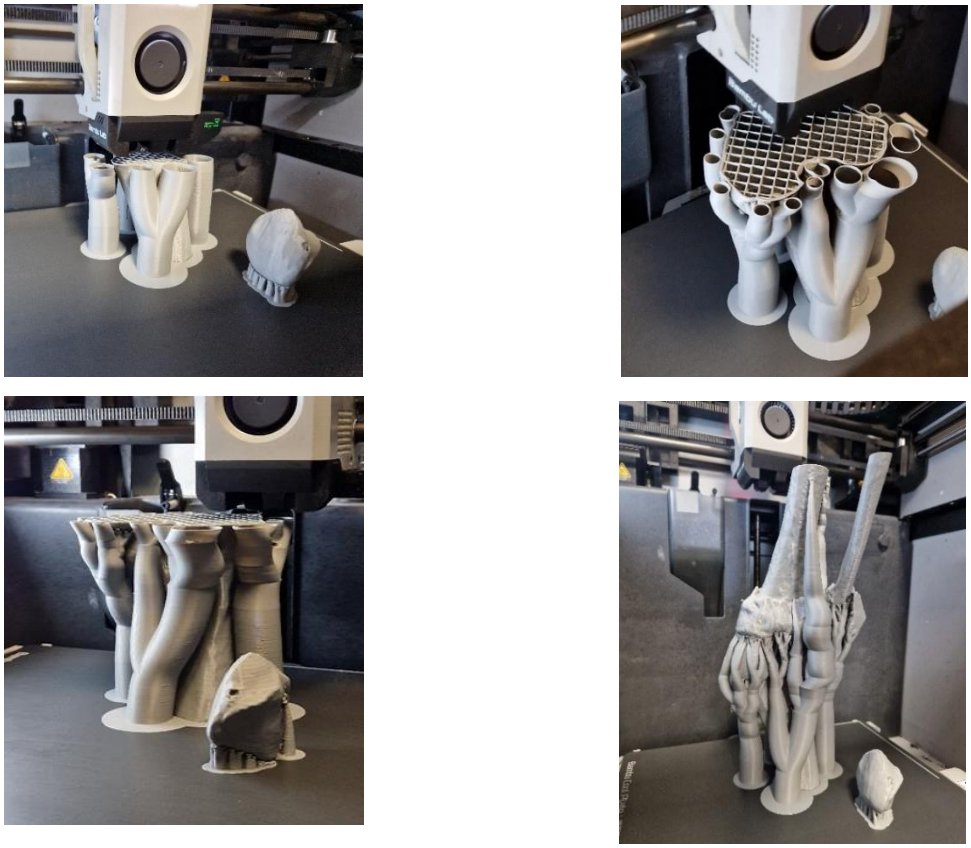
acquisition with a 0.6 mm layer. Spiral computed tomography involves a combination of continuous rotation of the lamp-detector system and table movement along the examined surface. A medical examination using a computed tomography scanner collects readings from the entire volume - including the layers of the organ. To put it simply: the head of a tomographic camera moves around the patient's body part and uses X-rays to take pictures in various planes. The examined body part, in this case the ankle joint, can be seen in 2D or 3D thanks to data transformation by computer software.

A 3D model of the knee joint was extracted from the medical browser and saved to an .stl file for 3D printing.



View 1 and View 2 a file in the 3D browser saved for 3D printing.

The next step was to 3D print the model, the stages of which are shown in the photos.



Stages of the 3D printing process – photos 1-4

Materials and Methods

The materials for the article consist of medical data of a patient with a knee fracture eligible for 3D reconstruction. The patient's examinations were performed in the form of computed tomography imaging – DICOM files. The medical examination revealed a comminuted fracture of the proximal tibia with a transverse fracture of both condyles just below the epiphyseal cartilage line – the description comes from the patient's medical examination. DICOM files were saved for 3D printing, which was printed using the layered method and subjected to a sterilization process.

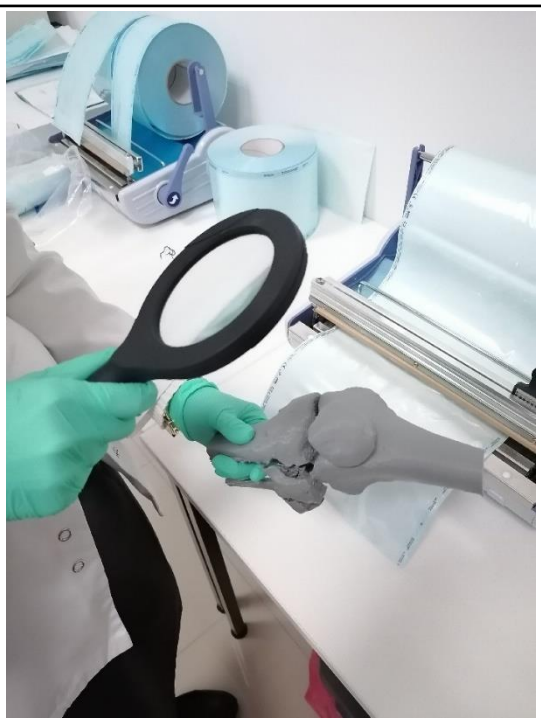
Results

The finished 3D model was subjected to a medical sterilization process. According to the World Health Organization (WHO), staff in the operating theater should have proof that the materials that will be used on the patient are sterile. Legal regulations impose an obligation on medical entities to properly sterilize medical equipment and devices. Sterilization is considered the only method of protection against microorganisms, i.e. protection against transmitted diseases. Disinfection is needed before the sterilization process is carried out. The disinfection process helps reduce the number of microorganisms found on medical tools and devices. The use of disinfectants or disinfectors gives a very good biocidal effect. To achieve complete neutralization, sterilization must be performed. Sterilization guarantees safety. Properly sterilized medical tools and devices are completely safe for both the patient and medical staff; of course, safety is guaranteed by maintaining appropriate standards at every stage of sterilization. The current conditions of the sterilization process include:

- Procedures and tools pose an increasing challenge to sterilization staff,
- Increased number of responsibilities, e.g. due to the pandemic,
- staff shortages,
- Number of planned and performed medical treatments and operations.

The 3D printed model of the joint necessary to perform a medical operation was subjected to the following stages of disinfection and sterilization:

Disinfection of the 3D model.



Disinfection control

Packing


Welding


Labeling, i.e. determining the expiration date of a medical device.


Low-temperature sterilization in an autoclave.

Low-temperature sterilization in an autoclave involved selecting a sterilization program with a temperature of 121°for porous samples, steam sterilization time approximately 29 minutes.

Potential sources of errors that pose a threat to the patient and medical staff include:

- human factor, including lack of appropriate education, up-to-date knowledge, and awareness of the risks associated with the sterilization process,
- equipment, lack of current regular services, poor water quality, lack of tests for the presence of Legionella bacteria in water,
-impact of the load in the autoclave, exceeding the weight, frequency of the load, type of sterilized material, autoclave configuration.

To prevent many errors during the sterilization process, it is important that the sterilization staff is aware of the risks and procedures, as well as chemical tests of the autoclave's purity and chemical indicators of the sterilization process. Proper sterilization means sterilization in an autoclave and selecting the appropriate sterilization program. To monitor the sterilization process and achieve proper control of sterilized medical materials, please refer to the documentation defining sterilization cycles. It is worth remembering that meeting all the requirements of the sterilization process is a formal obligation resulting from legal provisions.

Discussion

Forecasts of new applications

It is predicted that the use of 3D models developed on the basis of data from the DICOM file medical browser will become a permanent part of the patient treatment process in all fields of medicine. This will not only increase the quality of treatment, but also increase the level of safety of planned medical operations, increase the level of medical education, but also raise patients' awareness through educating them using 3D imaging and modeling. 3D modeling can be extended to display images in Virtual Reality (VR) and modify medical processes using artificial intelligence (AI).

Comparison with other options on the market

We can compare the printed 3D model of the knee joint based on the 3D printing materials used and how the material behaves (deformation, deformation, destruction) during the disinfection and sterilization process.

Conclusions

Medical DICOM file viewers are fully compatible with CAD software. Thanks to this, three-dimensional models can be created that can be printed using 3D printers. This allows for the rapid creation of implants intended for reconstructive medical surgeries. 3D medical products created using medical browsers and CAD software, using appropriate 3D printing material, can be safely disinfected and sterilized. The procedure of creating 3D models and printing implants as well as sterilization guarantees the safety of the patient and medical staff. Preparations for medical operations are significantly reduced thanks to 3D imaging and modeling. The use of modern 3D technologies shortens the patient's recovery time compared to traditional treatment methods. Modern medical technologies, including 3D printing, are used by experienced medical specialists, doctors undergoing specialization and medical students.

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DZ. U.2011.159.954 Conditions of remuneration for the work of employees of certain medical entities
Detailed sanitary requirements to be met by hairdressing, beauty, tattoo and wellness establishments
List of work stations and protective vaccinations recommended for employees starting work or employed in these positions
List of work that may result in transmission of infection to other people
Regulation on the qualifications of members of the hospital infection control team
Act on preventing and combating infections and infectious diseases in humans
Regulation of the Minister of Health of July 20, 2011 on the qualifications required of employees in particular types of job positions in medical entities that are not entrepreneurs
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