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Design and manufacturing of custom 3D printed bone implants

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HIGHLIGHTS

- Bone implants were designed, reconstructed, and manufactured from patient medical imaging data.
- Three models were manufactured at UrukTech in Baghdad and Sohar University in Oman.
- The 3D-printed final models had a perfect fit.

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ABSTRACT

In medical surgery, a customized implant is often required to meet surgical requirements, especially in cases with complicated or traumatic deformities. The emerging techniques of additive manufacturing, e.g., 3D printing, may help provide a quick response to such needs, provided that a valid approach capturing required implant shape data is generated and processed to better suit 3D printing. Different materials, including biocompatible polymer and metal, may suit medical-surgical applications. In this paper, an investigation is conducted to assess 3D printing technology use as part of a full system, from capturing implant shape data to producing the customized implant. The investigation is supported by experimental studies of medical cases. The first case aimed to produce shatter-related finger distal phalanx implants, whereas the second aimed to design and reconstruct a suitable cranial implant for a patient with a left frontoparietal skull lesion. For these cases, the study has adopted a scenario based on CT scans to generate the required implant shape data; hence using DICOM format. The captured data from the two cases are processed using a developed systematic processing approach to generate the final design of the required customized implants. The designs are then converted into suitable manufacturing codes for 3D printed plastic and metal prototypes enabling the assessment of the technique utilizing the facilities of UrukTech Company in Baghdad, Iraq, and Sohar University in Oman. Results show that the developed approach, from data capture to 3D printed implants, has succeeded in addressing the need for customized implants. For instance, the accuracy of the cranial implant was confirmed dimensionally, aiding in restoring structures, appearance, and psychological stability. The design and manufacturing of custom 3D-printed bone implants represent a significant advancement in medical technology and orthopedics, provided that biocompatible materials are used. Therefore, the technique may be adopted in the near future to serve the medical surgery field. The developed approach in this study encompasses several key ideas, contributions, and significant results, including creating patient-specific bone implants by utilizing medical imaging and 3D printing. Hence, the developed approach enables the creation of complex implant geometries that otherwise would be challenging to manufacture.

1. Introduction

The utilization of 3D printing [1,2] in the medical field has significantly increased. This is mainly due to the recent technological advancements that have enabled precise customization to match a patient's anatomy. Consequently, it is now feasible to design personalized prosthetic limbs, cranial implants, and orthopedic implants like hips and knees [3-5], leading to an increased demand for customized implants, prosthetics, and parts. Geometries and structures are becoming progressively

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complex, requiring rapid and precise manufacturing of products, including customized implants [6-10]. This study focuses on two main aspects to demonstrate the potential of developing such a field. These aspects are the hand bones [11-14] and cranial abnormalities in neurosurgery cases (craniolacunias). For the second aspect, regardless of the location of the semi-flat portions of the skull, bespoke skull implants offer the most effective correction technique while prioritizing brain preservation and aesthetics in cranioplasty.

Despite the significant importance of 3D printing in the medical field, only a few research papers address the development of a comprehensive system for designing and manufacturing custom 3D-printed bone implants. In their study, Kim et al. [15] demonstrated a method for evaluating and designing cranial implants to address significant skull anomalies. This approach not only reduces surgical risk but also accelerates the recovery process. It enables the manufacturing of large-scale skull components according to specific design characteristics. The design of the cranial implant was adjusted to suit the patient's basic operating conditions using the finite element method. These cranial implants were manufactured through injection molding and were successfully implanted in the patient. Marreiros et al. [16] provided the required CAD tool for creating neurocranium implants by employing symmetry principles and the best-fitting shape to estimate missing data within the radiologic volume data. Additionally, this approach utilizes a boundary fitting mechanism to achieve precise implant fitting. The smooth implant surface, which follows the main curves of the border and lacks sharp edges, allows for accurate intraoperative implant placement at the defect location. Castelan et al. [17] presented a method to create physical models of fractured skulls at a low cost prior to surgery, accompanied by custom titanium sheet implants. The implants are fabricated using incremental sheet forming, while the models are produced through 3D printing. By utilizing CT images of the injured skull, the authors reconstruct both the model's defective part (biomodel) and the restorative component (implant). Nasr et al. [18] aimed to utilize rapid prototyping (RP) technology to create, test, and construct prostheses of four Proximal Interphalangeal joint prostheses (PIP). Finger joint arthritis represents a significant pathological dilemma characterized by intense pain, stiffness, and deformity. These symptoms result from inflammation due to the disease, which includes synovial edema, ligament and muscle stiffness, and joint degeneration. Arthroplasty represents one of the surgical options for treating arthritis, involving replacing the affected joint with an artificial one. Beltrami et al. [19] focused on the uncommon presentation of GCT in the phalanx, which carries a high recurrence risk, and described its treatment for the first time. Modern metal 3D printing techniques rapidly produce personalized implants tailored to the patient's anatomy. In this instance, a unique titanium prosthesis was inserted following the failure of conventional aggressive therapy. After two years, the patient had achieved a fused first interphalangeal joint, a stable and functional MCP joint, and excellent overall reconstruction. Beltrán-Fernández et al. [20] made an effort to design and develop a tridimensional electronic prosthesis to replace the phalanges of a patient's left hand after the patient suffering severe burns requiring partial amputation surgery. The researchers created the prosthesis by dividing 539 pictures from a CT scan into segments and then delineating and separating the contours.

Motivated by the above research papers and discussions, in this paper, an investigation is made to assess the use of 3D printing to offer patients specialized implants to support surgeons in performing their tasks. Hence, two cases of customized implants are presented and discussed. The first case encompasses the replacement of shattered finger distal phalanx [21-23] implants tailored to individual patients, utilizing CT scans in DICOM format (Digital Imaging and Communications in Medicine format). The second case involves designing a customized cranial implant as a virtual model for preoperative planning to mitigate potential patient issues. Adequate preoperative planning is essential for elective surgery [24-27], such as technical planning for the distal phalanx finger and the skull bone required before surgery. Computed Tomography (CT) scans create three-dimensional (3D) reconstructions of the patient's anatomy in a virtual environment. Surgical procedures are then designed using these models to determine implant size, type, and placement in accordance with the standard of preference [28-30]. Thus, the objective of this manuscript is to utilize patient CT scan data to create a 3D CAD model of the shattered distal phalanx of the finger and the patient's skull's 3D reconstruction through a developed procedure. This procedure aims to preserve the original anatomy as much as possible using modeling software, specifically Mimics (advanced 3D medical image processing software) and 3-matic (3D data and design optimization software), demonstrating the application of 3D printed virtual implants and computer engineering in medical practice.

In contrast to current methodologies, this study's primary contribution and innovation include designing a customized 3D-printed implant tailored for the patient's finger's distal phalanx and the left frontoparietal area of the skull. The design process involves 3D CAD modeling using Mimics and 3-matic to refine the design and geometry. Employing 3D reconstruction techniques from medical images minimizes surgical errors, ensures a precise fit, and enhances implant stability. As previously mentioned, the finger's distal phalanx production followed a three-stage manufacturing process. In the final stage, the ultimate model was fabricated in metal to replicate the patient's finger bone closely. The cranial implant model was validated in dimensions, restoring the patient's appearance, psychological well-being, and structural integrity. This outcome provides a plausible course of therapy for patients. If intact bone tissue remains, our approach offers a foundation for developing patient-specific implants modeled from this bone tissue. The cranial implant model's dimensions, appearance restoration, psychological well-being, and structural integrity were thoroughly verified. This successful outcome paves the way for a credible therapeutic option for patients.

This study provides doctors with a formidable resource to improve overall patient outcomes. Also, the design and manufacturing of custom 3D-printed finger distal phalanx replacements and cranial implants represent a cutting-edge approach that offers tailored solutions for individuals with specific anatomical needs. This paper is organized as follows. Materials and methods are briefly discussed in Section 2. Section 3 presents the practical research design and manufacturing. The results are presented in Section 4, and various aspects of this research are discussed. In section 5, the conclusions are provided.

2. Materials and methods

The methodology of this paper begins with the Data Acquisition phase, during which CT scan slices of the region are captured using a CT scanner. The CT scan images, in DICOM format, are imported into medical image processing software, specifically Mimics (Materialise NV, Belgium) and 3-matic, for constructing the 3D image. The designed 3D model is then saved in STL format. Following this, a part of one case is printed in three models: a first model made of PETG plastic, a second model from PETG plastic after processing in case of defects, and finally, a third model made of metal. The various steps in the design and printing approach are depicted in the workflow overview in Figure 1.

3. Practical design and manufacturing

This section will cover the stages of designing and manufacturing a patient-specific implant. It will present two case studies. The first case involves a 20-year-old patient with an injury to the distal phalanx of the third finger of his right hand. The second case involves a male patient who fell from a significant height and requires the construction of cranial implants. The stages of implementation for the replacement with a custom implant will be explained.

3.1 Collection of CT scan data

The patient data was obtained from the Department of Radiology at Medical City, Baghdad, Iraq. Anatomical models of the patient were constructed based on Digital Imaging and Communications in Medicine (DICOM) data from CT scans [31].

3.2 Anatomical data modelling using mimics

Anatomical modeling: Using the criteria built into the simulation for querying the DICOM data, most of the bone tissue was separated from the patient's other tissues [32-34]. In this study, Mimics is used to construct 2D images and create a 3D CAD model to reconstruct unique implants comprising encapsulated soft tissues and bone structure. It is possible to view, segment, and display objects from 2D DICOM pictures produced by CT scans in 3D by importing them into Mimics software, which includes interfaces for all main scanner formats. The Segmentation, Simulation, and Import/Export modules are all part of the Mimics program [35-38]. The slice pictures produced by the CT scan can be automatically imported into the Mimics software [39]. The pixel size and slice distance ensure constant dimensional repeatability for the models developed during segmentation[40]. The following procedures are followed in the Mimics program to create a 3D CAD model:

3.2.1 Starting the project, adding DICOM images and Image organization

The import module supports various file formats, including the widely recognized DICOM format, for importing 2D stacked, uncompressed medical images from CT scans. Within this module, we could specify the necessary slices that constitute the item being considered. Therefore, successful converting DICOM files to Mimics format is gained, especially by benefiting from the option to omit poor-quality slices, as demonstrated in Figure 2.

3.2.2 Thresholding

The process of creating a segmentation mask begins with thresholding. The segmentation object, represented as a colored mask, will only contain picture pixels with values larger than or equal to the threshold value, as determined by the thresholding process. The segmentation mask includes all pixels falling between the higher and lower thresholds when they are required. Only the dense sections remain selected with a high threshold. An upper and lower threshold is required when the nerve channel must be chosen. The choice of threshold value depends on the desired outcome of the model. In Figure 3, the thresholding process is shown that allows soft tissue selection of the scanned patient using a low threshold value where the threshold window in mimics is shown in Figure 3 (A), the use of thresholding to isolate bones for the skull case is shown in Figure 3 (B). Any pixel with a grey value in that range will be highlighted in a mask. This will lead to the view of a certain part of the body (i.e., bones) by selecting suitable threshold values in the medical picture. The aim is to separate the bone data, e.g., the skull and distal phalanx cases, which have been studied in this paper, from other features, e.g., soft tissues. The medical images represent the density by the pixel-grey level value. Therefore, by application of the threshold process, the isolation of darker pixels will enable the focus to be solely on the bone in the image.

3.2.3 Region growing

Growing regions will remove noise and divide unconnected structures. The segmentation produced by thresholding may be divided into several objects, and floating pixels can be eliminated using the region-expanding tool shown in Figure 4.

3.2.4 Building 3D representations

The Project Management dialog arranges and interacts with the data (segmentation masks, 3D Calculate, objects, and STL). The 'Project Management > Masks' tab displays every generated mask and its corresponding threshold. The following command is used to compute a 3D part: 'Management of Projects > Mask Tab > Calculate 3D > Choose the appropriate mask (Yellow) > Calculate'. Mimics provides an adaptable interface that makes it easy to rapidly compute a 3D model of the area of interest. Hence, this will enable the adjustment of the resolution and filtering parameters. Every 3D model has attributes such as height, width, volume, surface, etc. With the ability to apply transparency and perform real-time rotation, panning, and rotating. Mimics can display the 3D model in the sagittal view. This process creates a 3D representation, as illustrated in Figure 5.

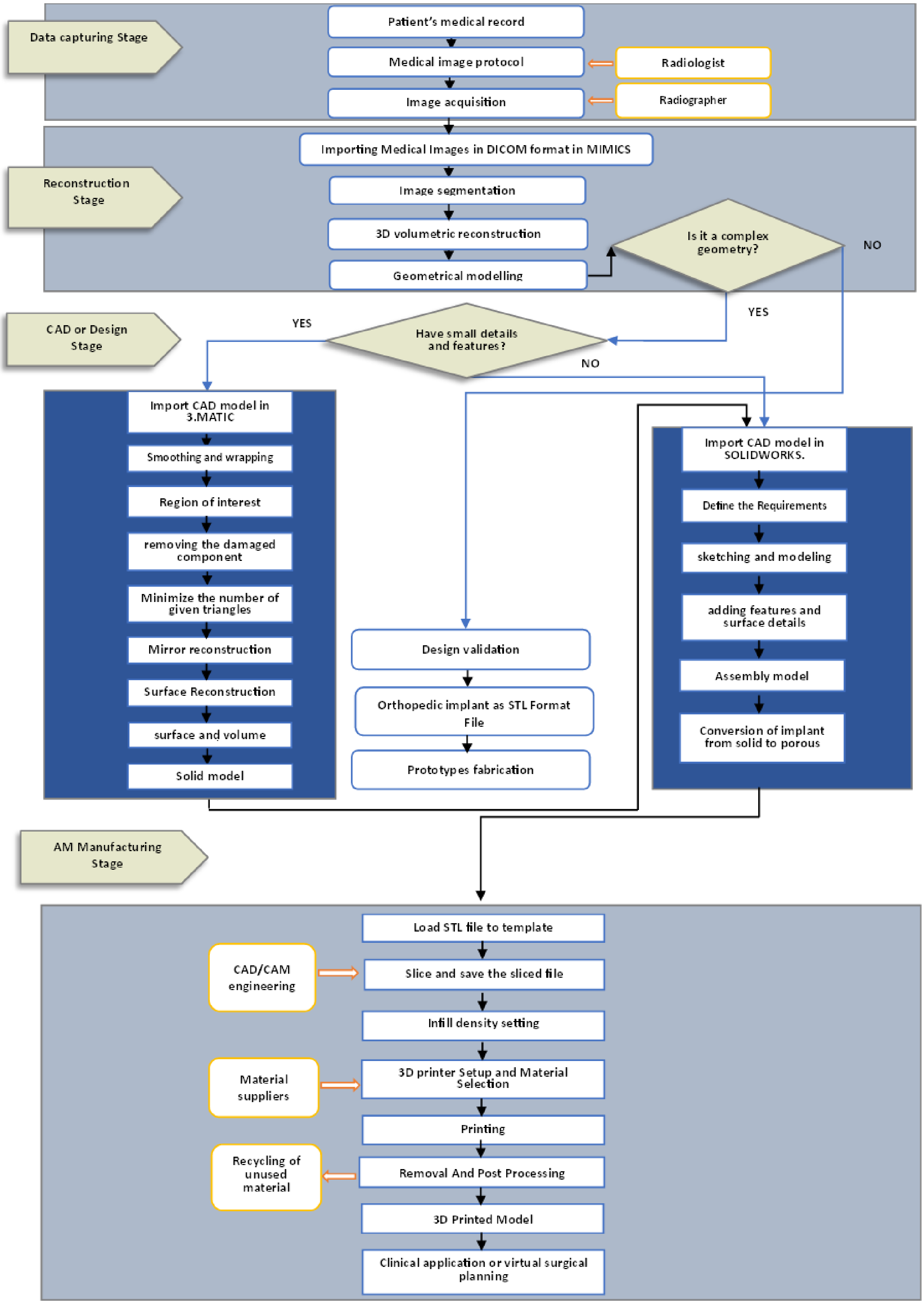


Figure 1: Methodology of Designing and Printing a Customized Implant

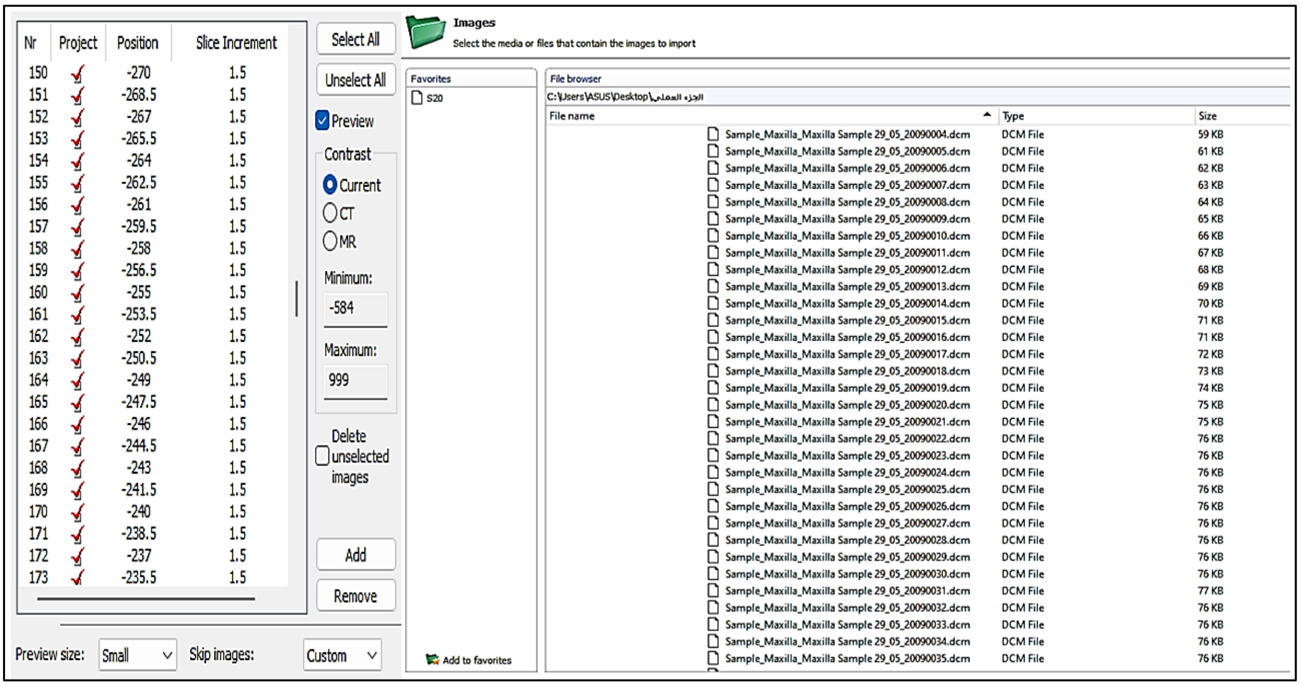
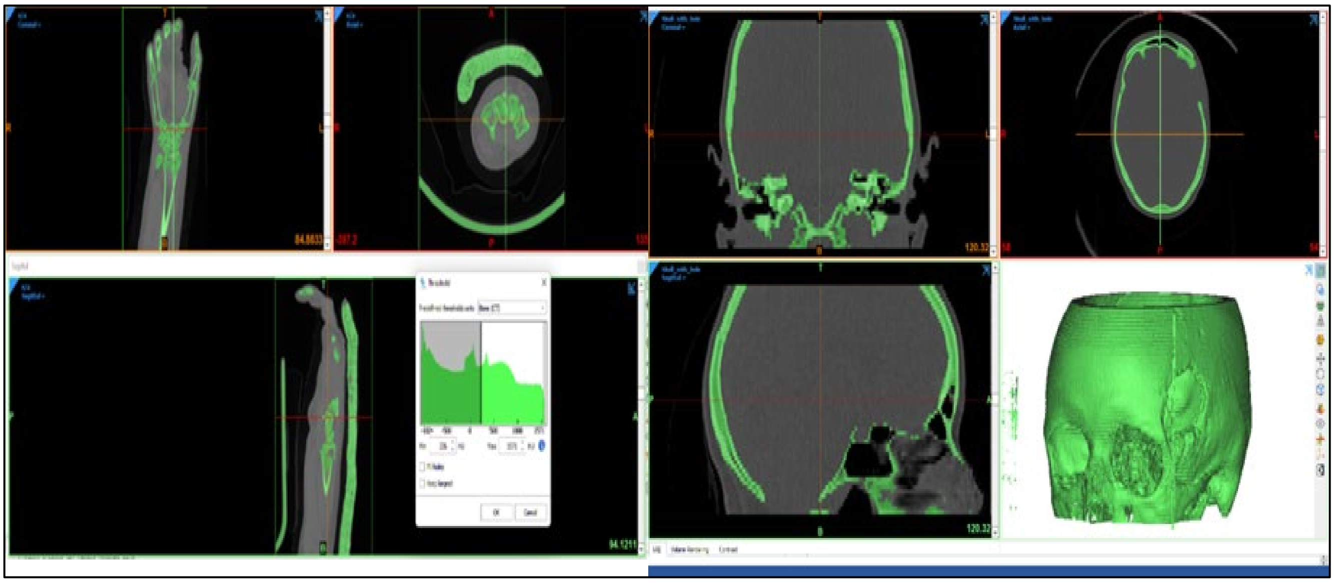
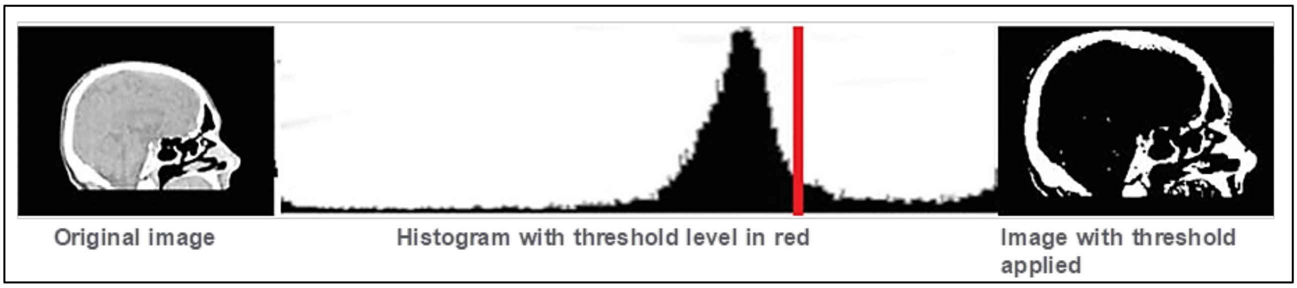


Figure 2: DICOM files being converted to Mimics files and Organize Images



(A)



(B)

Figure 3: Thresholding (A)Thresholding window in mimics (B) Using thresholding to isolate the bone for skull case

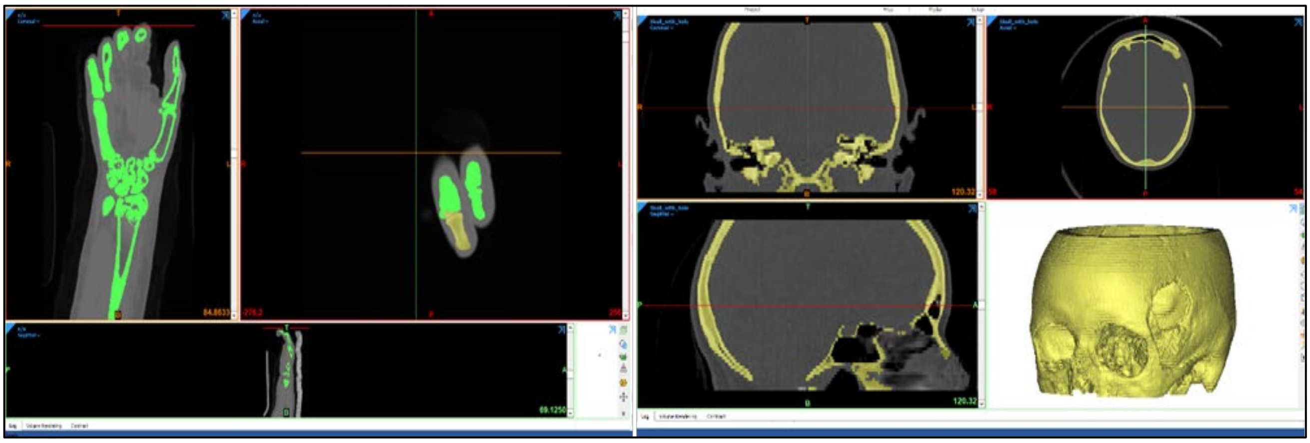


Figure 4: Region Growing

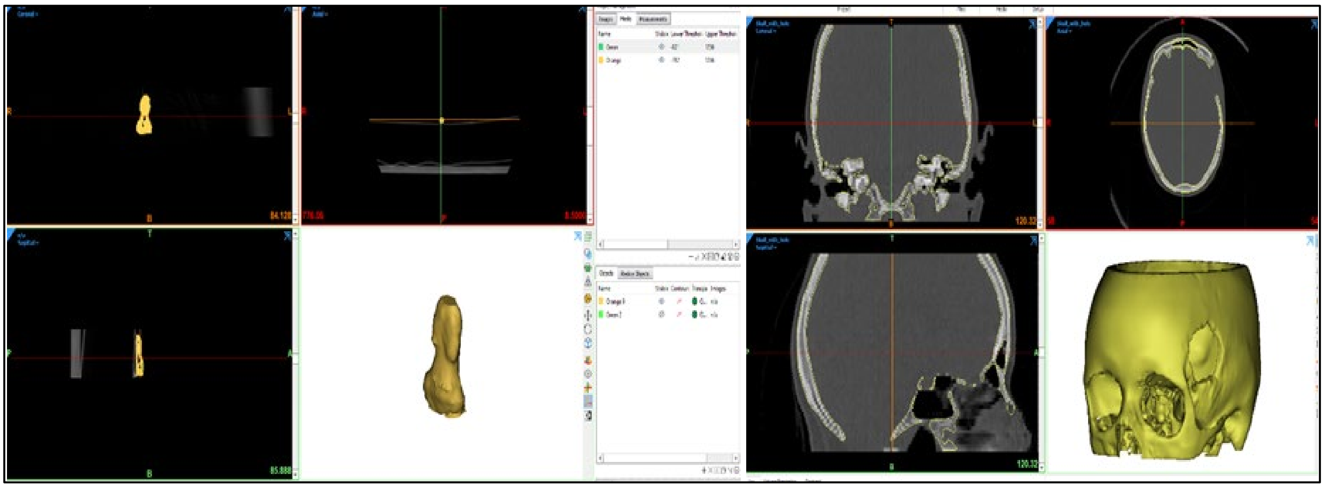


Figure 5: Creating a 3D Representation

3.3 Implant design

The final bone model from Mimics was imported into 3-Matic software. It is functionally comparable to SolidWorks but offers additional flexibility for modeling medical anatomy. Error correction was performed, ensuring the accuracy of the digital model. After the surface is generated, the model is automatically generated in volumetric form without the need for equations and determinants governing the drawing. This is achieved through the generalization of the volume mesh figure. Thus, we have automatically converted the image into a three-dimensional model completely similar to the required implant. It is necessary to adhere to the order of generalizations, as omitting any step leads to the failure of transforming the image. Finally, the definitive implant was generated from the patient's distal healthy phalanges using the capabilities of 3-Matic [28,30]. The skull geometry was determined, and a customized implant was designed using CAD software. The ideal model of the implant was created using the 3-MATIC program. To prepare the skull model, define the gap's shape and utilize points from the symmetric solid right section of the head bone. The determination of the datum plane was based on selecting three crucial points on the nose. Following the created datum plane, these locations were mirrored. Following that, Boolean operations were used to separate the required set of points for constructing the implant model and reconstructing the surface of the cranial defect. A CAD surface model was created by processing the newly created point cloud, which describes the 3D geometry of the implant. The cranial implant was created using different thicknesses, eliminating undercuts, and finalizing the cranial plate by smoothing, chamfering, and creating suture holes. Figure 6 shows the basic steps for the implant design based on the 3D reconstruction of the patient's skull, Whereas Figure 7 displays the final 3D CAD model of the distal phalanx created in 3-Matic. The model is then converted to the STL file format for use in slicer software to enable 3D printing parameter setup and printing. Topology imposes limitations in additive manufacturing design. Topology refers to the way components are arranged or connected. It's crucial to consider the construction orientation (i.e. z-axis) to optimize the part's functionality.

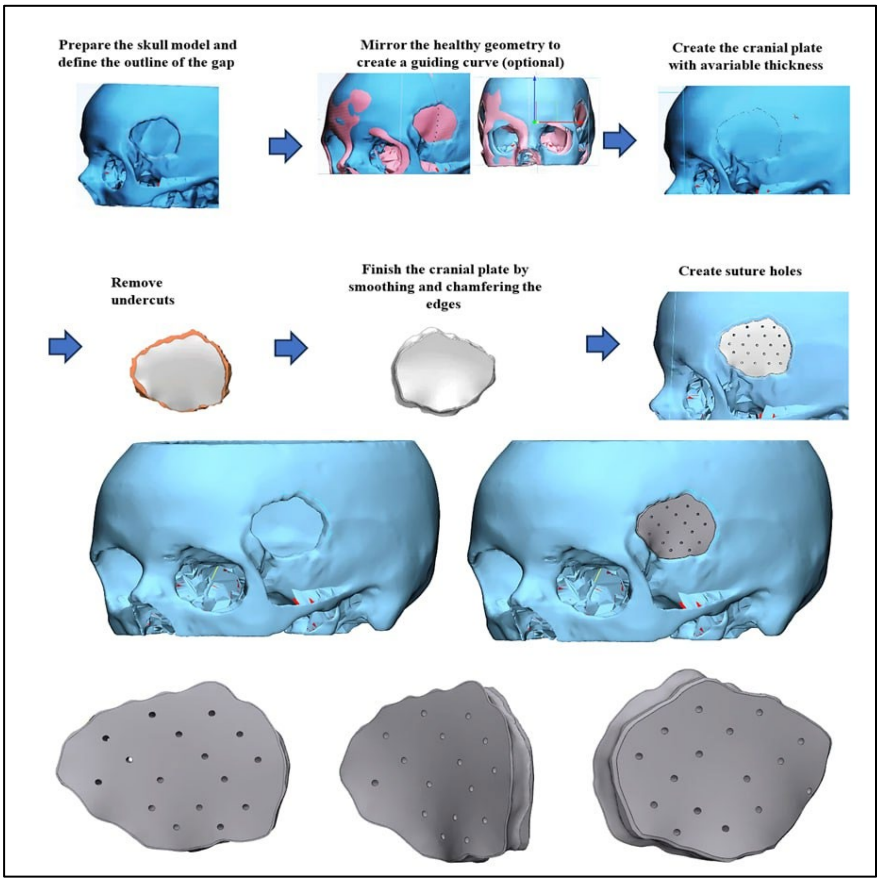


Figure 6: The Basic Steps of 3D Reconstruction for The Skull of The Patient

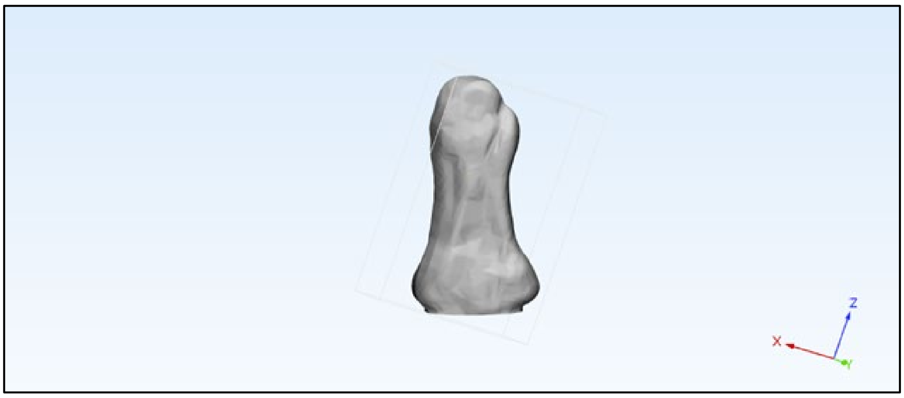


Figure 7: 3D CAD model in 3-Matic of Distal Phalanx

3.4 3D Printing implantation

Multiple phases are involved in the 3D printing of a finished object, including the choice of material, complexity of the product, intended usage environment, production cost, and the size and shape of the final product. The completed part may undergo post-processing after printing, including cleaning up leftover debris, cooling, annealing, drilling, cutting, and polishing. The first and second models were manufactured on the FDM printer at UrukTech Company in Baghdad, Iraq, to evaluate the dimensional accuracy and structural integrity. The model was found to print well, with no apparent issues with its structural integrity. In comparison, the final model was produced at Sohar University in Oman.

3.4.1 First Phase

At this stage, after the first implant model was completed by the software used (Mimics and 3-Matic), it exhibited holes and deformations, and then it was printed. Figure 8 illustrates the first virtual model of the 3D-printed finger distal phalanx in plastic before and after printing. Fused deposition modeling (FDM) printing using PETG plastic was employed for production. To validate the procedure and the plate before the actual surgery, plastic bone replicas were created and employed for a 'trial operation.' Step-by-step instructions were followed to attach the plastic bone model to the printer board using supports.

The printer was utilized for printing FDM models, allowing for a preliminary assessment of the model's print integrity. Table 1 summarizes the first virtual model's results.

3.4.2 Second Phase

The initial model was refined due to its initial issues with holes and distortion using Solidwork software before progressing to the final metal manufacturing stage. The second model was printed to verify all details before producing the final metal model, ensuring that it accurately matches the real object as designed in the CAD program. A low-cost fused deposition modeling (FDM) printing process using PETG plastic was utilized to produce the design. Figure 9 displays the second virtual model of the 3D-printed finger distal phalanx before and after printing. The summary output for the first virtual model is explained in Table 1.

Table 1: The Summary Output for the First and Second Virtual Models

Element	Value / Unit
The Name of The Material	PETG plastic
AM technology	FDM
Layer Thickness	0.2
The Type of Printer	CRIOS/ Modified / 600x300x400
(Build Time) The Time Required to Print the Implant	3 hr.
Printing Speed (Mm/S)	0.5
Post Processing Time	0.04 hr.
Build Material Weight	0.16 kg
Support Material Weight	0.04 kg
Machine Purchase Value	600 $
Useful Life Machine	10 years
Time Required to Setup and Build	4 hr.
Time Required for Performing Tasks	5 hr.

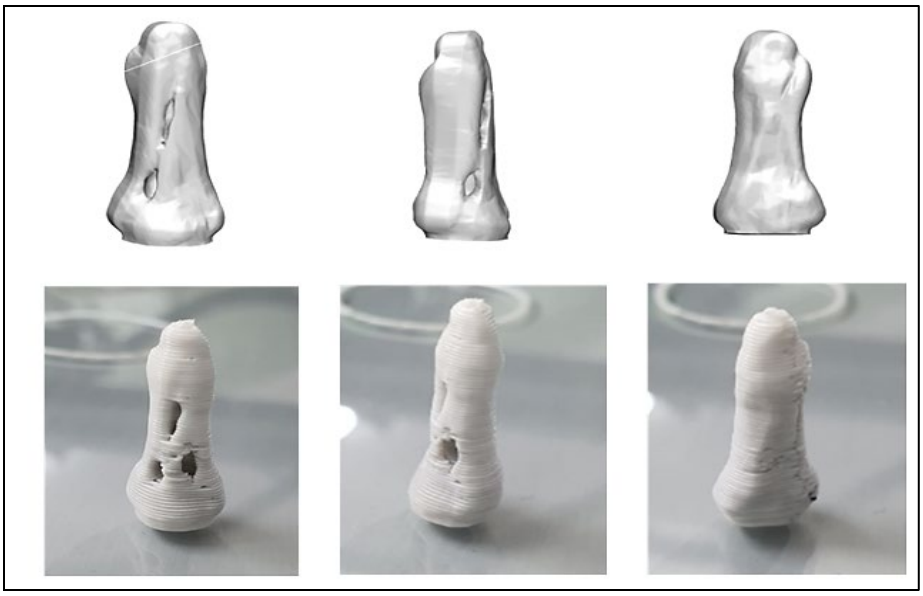


Figure 8: The First Virtual Model of 3D-Printed Finger Distal Phalanx by Plastic

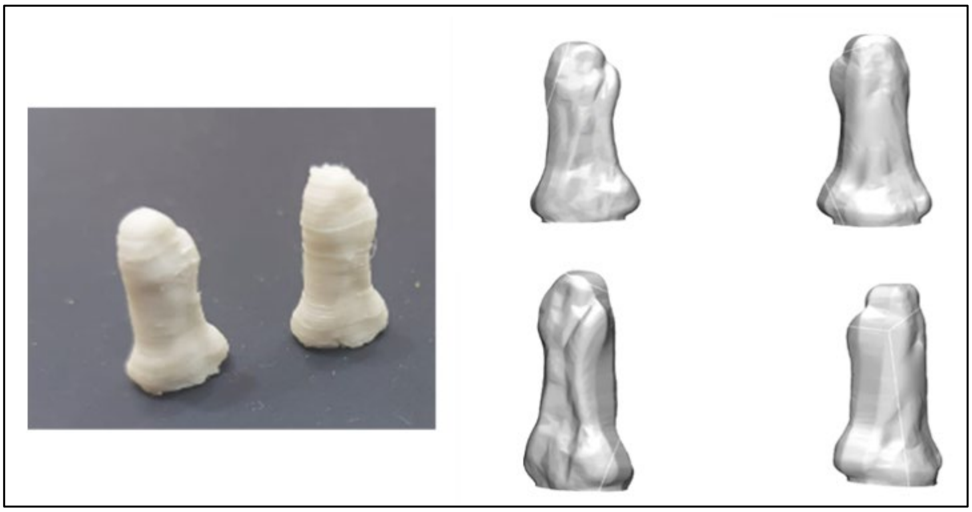


Figure 9: The Second Virtual Model of a 3D-printed Finger Distal Phalanx after Processing the Holes

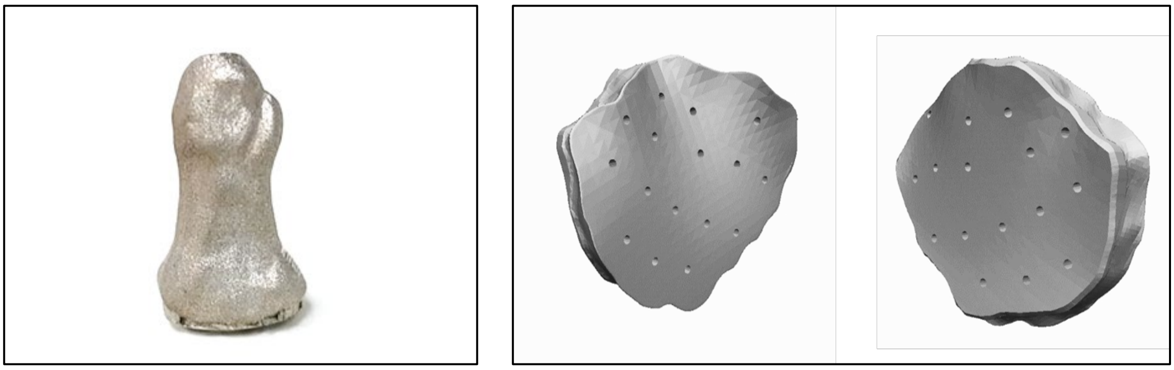
3.4.3 Final Phase

After completing the design using CAD programs and printing the first and second models to refine the design and address any defects, we arrived at the best model for adoption as the final implant. Subsequently, we proceeded to the final metal manufacturing stage. At this stage, the final model was crafted from metal to ensure a precise fit with the real bone. The 3D-printed finger distal phalanx and cranial implant post-processed from the front and side profiles, as well as the locations of the screw fixations, are shown in Figure 10 where distal phalanx is shown in Figure 10 (A), the cranial implant is shown in Figure 10 (B), and the summary output of the final implant is explained in Table 2.

The final model, manufactured using metal manufacturing, perfectly matched the patient's cranial defect and provided a symmetrical skull outline. The biocompatible implant will be made using the method for cranial reconstruction based on LPBF. Ti-6Al-4V, the suggested material, has been used in implants.

Table 2: The Summary Output of the Final Model of distal phalanx

Element	Value / Unit
The Name of The Material	Ti-6Al-4V
AM Technology	laser powder bed fusion (LPBF)
The Type of Printer	Xact Metal XM200G Printer
Build Volume in mm	150 x 150 x 150
(Build Time) The Time Required to Print the Implant	4 hours
Printing Speed (Mm/S)	10
Post Processing Time	1 hour
Build Material Weight	1.04 kg
Support Material Weight	0.12 kg
Machine Purchase Value	$92,000
Useful Life Machine	15 years
Time Required to Setup and Build	5 hr.
Time Required for Performing Tasks	5.5 hr.
Energy Consumed by AM System	5.5 kW



(A) (B)

Figure 10: The Final Models of 3D-Printed A) Distal Phalanx B) Cranial Implant

4. Results and discussion

The importance of the results obtained in this study lies in developing a systematic procedure to design and manufacture custom 3D-printed bone implants. The developed approach is validated by designing and producing metallic replacements for the distal phalanx and the left frontoparietal region of the skull. Significant findings are acquired from this study on the correlation and procedure adaptability among several employed computer software packages, including Mimics, 3-Matic, Solidworks, and 3D-Slicer, to custom and produce 3D-printed bone implants. One of the challenges in this research lies in the efforts required to experiment with software packages to assess their adaptability in the suggested systematic procedure. Several medical and geometrical modeling software have been tested by the research team to assess their functionality in meeting the aims of this research, including (but not limited to) the export and import of modeling formulas from one to the other. Ultimately, we have concluded that Mimics and 3-Matic are suitable to be employed in such systematic procedures to approach the design of custom bone implants. In contrast, Solidworks helps to refine the design and fill in missing data. The manufacturing stage uses the 3D-Slicer software to generate the required codes for 3D printing. Moreover, the ability to tailor implants to each unique patient's case needs fosters a more personalized approach to healthcare. In this study, the DICOM (Digital Imaging and Communications in Medicine) format is adequate to generate high-resolution images using CT scans for use in the developed systematic procedure.

One important issue to be considered is the proper selection of the material used for the 3D-printed bones. The usual material used for this case is Ti-6Al-4V due to its suitable properties and availability in the proper form for 3D metal printing to produce implants that match the patient's anatomy.

Furthermore, fused Deposition Modeling (FDM) 3D printing technology has been used in this research to ensure the correctness of the geometrical shape of the implant polymer-based prototype. 3D metal printing is an expensive process; hence, the approach adopted in this study is recommended. The approach is to use FDM 3D printing to produce a polymer-based prototype to inspect and ensure defect-free geometrical features of the implant before commencing 3D metal printing. In the acquired results of the 3D-printed finger distal phalanx, undesirable holes in the geometry were observed. Thus, these were eliminated by design refinement using Solidworks software before the commencement of 3D metal printing. Due to its low cost, the FDM polymer-based 3D printing is widely used in research, prototyping, and educational purposes.

Nevertheless, the acquired results in this research have indicated that the developed systematic approach has reduced the time required to create a customized implant for the patient, from the design process to manufacturing, based on the suggested steps and the employability of the identified software packages.

Overall, the design and manufacturing of custom 3D-printed bone implants have revolutionized orthopedic surgery since they offer personalized solutions with better patient outcomes and risks than traditional implants. This innovation continues to evolve, with ongoing research and development focused on enhancing materials, techniques, and patient care.

In the case of the cranial implant model presented in this paper, the dimensions are validated to restore the patient's appearance and structural integrity. This outcome provides a reasonable course of therapy for patients. Moreover, when intact bone tissue is still present, the developed approach offers a foundation for developing patient-specific implants modeled from this bone tissue. Thus, the findings of this study may provide doctors with a potent tool to enhance overall surgery outcomes.

The results obtained in this research further develop the suggested approach towards its fully automated. One way to approach such targets is by investigating the use of Artificial Intelligence tools to refine the design without needing human expert intervention. The developed approach is a promising approach to continue the research efforts in this direction, especially since the world is currently witnessing more and fast developments in 3D metal printing techniques.

5. Conclusion

This study suggests a systematic procedure to enable the full process, from capturing implant shape data to producing customized implant parts. The suggested approach is implemented experimentally to assess the potential of using 3D printing technology as part of the system. The example cases of the patient's finger distal phalanx and the left frontoparietal area of the skull have been used in the experimentation to demonstrate the validity of such a systemic procedure. The 3D CAD design of customized implants for the selected cases is created using MIMACS and 3-matic software. The design is refined using Solidworks software, whereas 3D-Slicer software is used to generate the codes for 3D printing. While the developed system has demonstrated its validity, it should be noted that any developed system may have certain limitations. However, such limitations could be overcome by properly selecting the processing parameters used in medical image processing.

The use of 3D reconstruction techniques from medical images helps to reduce the possibility of errors during surgery, improve fit, and enhance implant stability. Results presented in this research have demonstrated that even using such powerful processing tools, further attenuation of the design outputs must be handled by human experts to ensure the readiness of the part geometry in the 3D printing stage. Hence, doors are still open to researchers in this field to further develop and generate fully automatic systems that enable geometrical data capture from medical imaging to full manufacturing of customized implants.

The manufacturing part of the developed systematic procedure involves several steps: printing the product in polymer-based prototype, examining the printed prototype, refining the geometrical model (if needed and as required), and then commencing the 3D metal printing. This approach aims to reduce the cost as 3D metal printing is still expensive compared to 3D polymer printing. Therefore, printing the prototype using polymer-based printing will dictate whether design refinement is needed to ensure geometrical correctness and a defect-free model to be printed using the 3D metal printing technique.

In conclusion, the developed systematic procedure to design and manufacture custom 3D-printed bone Implants is demonstrated to offer tailored solutions for people with specific anatomical needs. While challenges exist, advancements in materials, technology, and medical research continue to push the boundaries of what is possible in prosthetics and orthopedics.

For future work, the developed systematic approach may be further investigated to assess its potential to develop medical imaging-based applications to manage trauma patients. Moreover, since the developed approach doesn't consider stress design analysis, conducting such a study would provide valuable future results.

Author contributions

Conceptualization, Z. Neamah . and L. Al-Kindi; methodology, G. Al-Kindi; software, Z. Neamah; validation, Z. Neamah, L. Al-Kindi. and G. Al-Kindi; formal analysis, Z. Neamah; investigation, Z. Neamah; resources, Z. Neamah; data curation, Z. Neamah; writing—original draft preparation, Z. Neamah; writing—review and editing, Z. Neamah; visualization, Z. Neamah; supervision, Z. Neamah; project administration, Z. Neamah. All authors have read and agreed to the published version of the manuscript.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

Conflicts of interest

The authors declare that there is no conflict of interest.

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