

Transforming Spine Surgery: CT-Guided Design of Personalized 3D-Printed PEEK Implants

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ABSTRACT

Reconstructing spinal defects continues to be a significant challenge in modern neurosurgery due to the complexity of their anatomy and individual differences in vertebral structures. This work embraces an innovative end-to-end pipeline in which artificial intelligence (AI), computer tomography (CT) imaging, and additive manufacturing are combined to create patient specific spinal implants made of PEEK. AI-driven segmentation and reconstruction models with cascaded 3D convolutional neural networks (CNNs) are used to automate the segmentation and reconstruction of anatomical models based on clinical CT datasets. High-fidelity anatomical models can be reconstructed for the computer-aided design (CAD) and 3D printing of custom implants tailored to each individual patient's anatomy; ultimately benefiting surgical accuracy, accuracy of implant fit, and postoperative outcomes using PEEK. PEEK has several advantages due to its radiolucency, biocompatibility, and mechanical compatibility with cortical bone. The Auto-Implant method allows for enhanced precision through curvature-sensitive modeling for ideal anatomical and cosmetic match. Evaluation on a synthetic and clinical dataset achieved sub-mm reconstruction accuracy and numerous endorsements from clinicians and appropriate anatomical accuracy of final implant designs, achieved through post-processing approaches and Gaussian curvature. We have demonstrated a reproducible and scalable AI assisted pipeline to personalize the manufacture of patient specific implants and perhaps the outcomes of surgical procedures, whilst facilitating more extensive personalized spinal reconstructions. Future directions will include continuing to expand clinical validation, enhance user interactivity with clinician input and build structured clinical trials to facilitate greater uptake and regulatory approval. This research has taken significant steps in facilitating the adoption of AI within surgical planning and implant design and has greatly advanced personalized, precision-based neurosurgical care.

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1. Introduction

Reconstruction of the spine presents some of the toughest challenges in modern medicine owing to the biomechanically very complicated anatomy of the vertebral column, the sensitive neurovascular structures in the neighborhood, and the peculiar anatomical variations found in every patient. Precision, personal approach, and time efficiency lead to improved patient outcomes, lesser time spent in the operating theater and reduced post-operative complications. Therefore, PSIs in spinal surgeries represent game changes with anatomical solutions customized for defect morphology and surgical objectives (Jain, 2025).

The convergence of AI, CT, and AM, itself popularly called 3D printing, has catalyzed the development of these custom-made spinal implants. AI-based algorithms assist in automated segmentation and formation of anatomical models directly from the high-resolution CT data, allowing implant design to an accuracy of a millimeter with a personalized fit (Ghai et al., 2025). Among the materials proposed for spinal PSIs, an increasing attention has been given to PEEK in that it is biomechanically compatible and superior to metal implants in radiological terms (Najm & Ali, 2024).

The present article provides an integrated overview of the design, processing, and surgical application of 3D printed personalized PEEK spinal implants designed via AI assisted interpretation of CT data and advanced techniques in additive

manufacturing. It thus goes on to demonstrate how this approach could considerably reopen the road toward spine surgery, improving patient protection, surgical precision, and implant lifetime.

2. Literature Review

Reconstructive surgeries can be extremely challenging for most surgeons due to anatomical complexity, the sensitivity of the implicated systems, and the uniqueness of each defect (Parthasarathy, 2014). The primary concern for surgeons is to reconstruct the defect in the best feasible manner with the least time spent on the surgical procedure in order to help patients recover and improve their wellbeing (Mohammed et al., 2016). A patient specific implant (PSI) is an effective solution that can be designed to fit precisely within anatomical defects or malformations. The need for creating PSIs has provoked several evolutionary and revolutionary technological developments in the medical field (Chae et al., 2015; Rengier et al., 2010).

Technologies, such as additive manufacturing (AM) or rapid prototyping (RP) or three dimensional (3D) printing, are significantly on the rise and have changed the biomedical sector for the best and for the greater in the past 10 years to allow utilization by surgeons and researchers for manufacturing objects (Attaran, 2017; Wong, 2016). AM has become a reputable place in the medical implant manufacturing industry, especially as it was introduced in the late 1980s, along with the shift from the old system of mass production of medical implants to a customized (truly patient) implant production system (Chua & Chui, 2016). Many organizations around the world are producing patient specific implants (PSI) using the various AM techniques using the computer axial tomography (CT) scan data obtained by the treating physician (Navarro et al., 2008). Recently, the US Food and Drug Administration (FDA) improved their approval of 3D printed implants under their 510k (premarket notification) approval process. This approval process now allows from AM manufactured anatomical models and/or medical devices to be used by the healthcare providers in both routine and the complex surgical cases (Mohammed et al., 2016).

Additive manufacturing works by creating a model from the ground up by depositing the material, layer-by-layer, in a controlled and operated manner, using digitally controlled and digitally operated labeling tools (McGurk et al., 1997). As a result, additive manufacturing is fundamentally different from both traditional forming and subtractive manufacturing because it is the closest manufacturing method to pure "bottom up" manufacturing. The additive manufacturing methods allow us to build a structure into its designed shape through the "layer-by-layer" principle. Layer-by-layer additive manufacturing affords us unprecedented freedom in producing complex, composite, and hybrid structures with control and precision that cannot be made through traditional manufacturing routes (McGurk et al., 1997). Capturing a quality image is essential to producing accurate 3D printed models. Advances in imaging modalities now allow for more accurate patient specific anatomical models. Moreover, advances in segmentation software and tools have provided the ability to explicitly extract the surfaces of the structures of interest from 3D medical imaging data rapidly and increasingly automatically or semi-automatically (Lioufas et al., 2016; Vezzetti et al., 2016).

With all of these advances, additive manufacture (AM) has become a commercially commonplace manufacturing technology within medicine to produce anatomical models, surgical implants, surgical guides, external aids, and biomanufacturing (Gil et al., 2015; Haefeli et al., 2015; Honigsmann et al., 2016; Javaid & Haleem, 2018; Mazzoni et al., 2015; Melchels et al., 2012; Rana et al., 2015; Schwarzkopf et al., 2015; Shengwei et al., 2014; Tuomi et al., 2014; Wilasrusmee et al., 2008). Many studies have been published about AM applications to produce surgical instruments and biomaterials, and a variety of biological tissues including 3D printing of cells, blood vessels, vascular networks, bones, ears, windpipes, dental prosthetic (including a jaw bone), and in the future corneas (Schubert et al., 2014). Surgeons can produce 3D printed hand-holdable models (commonly referred to as bio models) for the surgical task to educate the patient, plan the surgical approach, and as an intraoperative surgical guide. These 3D printed medical models are being widely used in orthopedic, cardiac, dental, and craniomaxillofacial surgeries as a means to improve treatment for patients (Hieu et al., 2005; Kaye et al., 2016; Martorelli et al., 2016; Sanghera et al., 2001; Winder et al., 1999).

There are now numerous technologies for additive manufacturing (AM) such as stereolithography (SLA), photopolymer jetting, selective laser sintering (SLS), electron beam melting (EBM), and direct metal laser sintering (DMLS), as well as the more familiar fused deposition modelling (FDM), or fused filament fabrication (FFF) (Dickens et al., 1995; Hoang et al., 2016). These technologies were originally developed for the manufacture of solid objects for the planning of surgical procedures; however, they have now become a significant part of surgeon's tool kits for reproducing anatomical objects as 3D physical models and use is being considered in the reconstruction of patient specific implants (PSI). There potentially exists a wider variety of alloplastic materials-both metals and ceramic, polymer, and composite materials that can be fabricated using AM technologies and used as substitutes in reconstructive and orthopedic surgeries. Also, because alloplastic materials are factored as abundant meaning donor sit morbidity is not a concern, which represents a huge disadvantage for incumbents of autologous grafts (Rohner et al., 2003). The commonly used metallic implants utilized in hospitals can be classified as permanent prostheses (e.g. knee and hip prosthesis, cranial prosthesis, dental implants) and temporary implants (e.g. plates, pins, screws, and rods for the fixation of bone fractures). All metallic implants have very favorable mechanical strengths, friction-resistance and are the preferred alloplastic material for additive manufacturing AM

in the category of manufacture of orthopedic implant (Adell et al., 1981; Jardini et al., 2014). Their high load bearing capacity and resistance to loading does not equate to the normal human bone tissues and can lead to stress shielding and ultimately prosthetic loosening. Metal has a high X-ray absorption compared to the surrounding tissues which typically cause streak artifacts in CT scan imaging. In addition, many metals will be magnetic resonance imaging (MRI) incompatible thus limiting the options of examining the patient with MRI. The introduction of metals to an in vivo environment can also create the potential for a hypersensitivity reaction and result in osteolysis (Ma & Tang, 2014). Due to these limitations, ceramics have been investigated as an alternative biomaterial. Generally speaking, of the ceramics, metallic oxides, calcium phosphate, and glass ceramics are used as these ceramics are associated with a favorable toxicity profile, good biocompatibility, and bioactivity. While the ceramics have good initial mechanical properties, (including but not limited to acceptable strength and rigidity), the ceramics have inadequate design mechanical properties (e.g. low toughness and ductility) combined with high modulus of elasticity, resulting in inadequate mechanical properties for load-bearing applications (Kokubo et al., 2003). Because of the myriads of limitations noted with metallic and ceramic biomaterials, the use of polymers is being investigated as a more recent biomaterial alternative. Some common polymers include ultrahigh molecular weight polyethylene (UHMWPE), polymethyl methacrylate (PMMA), polylactide (PLA), polyglycolide (PGA), and polyhydroxybutyrate (PHB) as these polymers are used across a number of biomedical applications. However, there are a limited number of polymers that are utilized for bone replacement functions, largely due to polymers' excessive flexibility and weakness for orthopedic and load-bearing implant applications (Ramakrishna et al., 2001). Polyetheretherketone (PEEK), amongst the plethora of alloplastic materials, has stood out as a viable option for the PSI. PEEK is a semicrystalline linear —polycyclic aromatic thermoplastic. PEEK is classified in the linear aromatic polymer family and comprises repeating units containing ether and ketone linkages (Ma & Tang, 2014). PEEK was developed by a team of scientists from England in 1978 (Eschbach, 2000).

In the 1980s, PEEK was used as aircraft and turbine blades. By the late 1990s, PEEK was used to replace components of metal implants, and in orthopaedic and trauma specialties PEEK substituted metal implants entirely. Today, using PEEK in different applications has been possible due to its unique properties including high-temperature performance, chemical resistance, fatigue resistance, lightweight, high yield strength, stiffness, and durability (Sanghera et al., 2001). PEEK polymer has been explored for manufacturing and 3D printing in various industries to a great extent; however, using PEEK in the medical field has noteworthy challenges related to its physical properties (Stansbury & Idacavage, 2016; Vaezi & Yang, 2015). This article will discuss the technological and early-stage outcomes on the material extrusion (FFF, 3D printing) based manufacture of PEEK parts discussing PSI for surgical use of said parts.

PEEK is a superlative biocompatible thermoplastics polymer with mechanical properties, specifically modulus of elasticity selected for the close association with close cortical bone to mitigate against the risk of stress shielding and promote osseointegration. PEEK is radiolucent and therefore does not create artefacts on postoperative CT and MRI scans to be able to visualize the bony structures, this is especially useful for spinal surgeries either limitations in patients from metals in MRI or artefact in CT interfacing with as they navigate the post-operative implications. PEEK is also chemically stable and has high mechanical strengths with fatigue resistance and is lightweight making it exceptional for the spinal applications designed for load bearing.

The use of AM in orthopedics has predominantly based considerations mainly in development reference to static models and surgical guides, with the evolution of AI through the likes of imaging, segmenting software and advances in material sciences have led to more refined and functional constructions. The recent advances include AI-mediated work flows, note machine learning when segmented, anatomical modelling and even implant personalization derived from CT datasets (Dunka et al., 2021). The use of AI would significantly shorten design cycles, decrease human errors and improve the clinical implications of 3D-printed implants. The constraints of traditional materials including metals and ceramics have also led to the shift to PEEK. Metal implants such as titanium and cobalt-chromium are certainly strong, but are linked to image artifacts, differences in elastic modulus, and hypersensitivity or prolonged osteolysis. While ceramics are biocompatible, they lack fracture toughness and ductility that makes ceramics unusable in dynamic and load bearing procedures of the spine. 3D printing has changed the game in terms of creating complex geometries, not only those that are lighter and easier to manage but also lighter lattice structures designed for the individual patient. Technologies that contribute to individual 3D printing comprise fused filament fabrication (FFF), selective laser sintering (SLS), and direct metal laser sintering (DMLS) which all allow for layer -by-layer construction of PSIs with anatomical accuracy. 3D printed models have transitioned from being simply surgical planning tools to current implantable products, improving mechanical properties and sterilization protocols. Regulatory approval is evolving too. Since PEEK has been increasingly utilized for 510(k) clearances, specifically for AM processes, the number of safety and efficacy approvals by the FDA have increased too. Therefore, the coexistence of AI, CT imaging and 3D printing with support ongoing use of PEEK and its promise of changing typical spinal interventions to more personalized and outcome based surgical procedures.

3. Datasets Description

Data utilized for study were sourced from two sources, the clinical imaging data associated with the National Medical Center (NMC), and publicly available CT imaging datasets respectively. The primary dataset accounted for high resolution

computed tomography (CT) scans of patients that needed spine reconstruction and acquired in Digital Imaging and Communications in Medicine (DICOM) format. These DICOM files contained axial slices of between 0.3 mm to 0.6 mm thickness, affected by the scanned region and provided sufficient anatomic detail necessary to accurately model and reconstruct depending on how the 3D digital model was planned. The DICOM data was imported into a medical imaging computer software program (Mimics, Materialize, Leuven, Belgium) used for anatomical modeling within the DICOM interface. Using threshold-based imaging segmentation procedures specific for bone tissue in grayscale intensity value, the spine bone structures of interest were segmented from all spine structures. The segmentation process provided 3D virtual modeling data in axial, sagittal, and coronal planes. The segmented models were exported into 3-Matic (Materialize, Leuven, Belgium) for further surface refinement, implant design, and geometry personalization. Final 3D implant models were saved as standard tessellation language (STL) files. The STL files were used in the fused filament fabrication (FFF) 3D printing of patient-specific implants (PSIs) using medical-grade polyether ether ketone (PEEK).

4. Search Strategy

Our search strategy was designed to locate peer-reviewed clinical/trials that were relevant to AI-informed precision CT Imaging: Custom 3D printed PEEK Implant for spine reconstruction. The search was designed to include research studies that focused on the use of artificial intelligence in CT Imaging, as well as studies that explored the development of patient-specific 3D printed PEEK implants. Databases searched from inception included: Medline (via OVID), PubMed, Embase (via OVID), and Cochrane Library. To maintain relevance and quality, non-English publications and review articles (including narrative reviews, literature reviews, and systematic reviews), were excluded. The detailed search strategy and inclusion criteria are included in the Supplementary Information.

5. Methodology

This section outlines the execution of an AI based machine learning model to obtain an accurate CT imaging style for reconstructing vertebral structures to design and manufacture patient specific, 3D printed PEEK spinal implants. The model is based on a cascaded 3D Convolutional Neural Network (CNN) machine learning model and also aims to reconstruct the damaged vertebrae from CT data and build implant design in an automated or integrated workflow. This study used two distinct datasets: a synthetic vertebral defect dataset (Spine Break) that could be manipulated with precision, and a clinical in-house dataset obtained from CT scans of patients with spinal defects with clinician validated reconstructions and implant models. All datasets underwent standard preprocessing including segmentation, rigid alignment, and voxel normalization to standardize the data for model training and implant design generation.

5.1 Data Collection and CT Scan Processing for Spinal Vertebral Reconstruction

For this study, we utilize clinical CT scans to create accurate, patient specific spinal implants. Our primary dataset was achieved by TESCO Medical and includes expert validated segmentations and reconstructions of the spinal defects. We realized that previous literature was limited by not making readily available, publicly/reproducible imaging databases, we developed an automated processing pipeline from CT scans of the National Medical Center (NMC) spine database in Karachi, Pakistan to create a synthetic vertebral defect dataset, one that included clinically relevant cases.

In order to keep anatomical consistency, the processing pipeline has several important steps. Alignment will ensure that all vertebrae will have standard anatomical body geometry, for instance, alignments along the anterior and posterior axis and vertebral endplates, that will reduce variability and increase fidelity when restoring geometry. Segmentation involves separating vertebral structures of interest from surrounding tissues using standard and deep learning segmentation methods, while focusing on the pedicles and endplates. Normalization will rescale the voxel dimensions in those datasets to assure standardized anatomical proportions. Finally, defect simulations will add realistic pathological and surgical defects to the vertebrae such as lytic lesions or burst fractures and post laminectomy changes with both smooth and jagged edges. Collectively, these processes provide for robust training of the model and contribute to a public dataset that furthers the state of the ballast in vertebral reconstruction.

5.2 3D Reconstruction Model Architecture for Vertebral Completion

At the heart of the research is an automated system for vertebral structure reconstructions with a cascade 3D convolutional neural network (CNN). The authors conceptualized the task of vertebral reconstructions as a volumetric completion problem, with the reconstruction defined as the estimation of the anatomical structure $Y = X_{\text{healthy}} - X_{\text{defective}}$ the volumetric slices by taking into consideration the expected input but ignoring the defective slice. The system has been trained with synthetic ("Spine Break") and real-world clinical data. The model architecture leverages a two-stage cascaded architecture to balance the contextual information and the accuracy of the reconstructions. Both stages of the study were capable of operating on low-resolution models f_{Lo} with down sampled 64^3 voxel inputs (which is around 2-3 mm/voxel)

and the first stage has been implemented as a modified 3D U-Net architecture. Nearest-neighbor up sampling after the first projection followed by appending a convolutional layer was executed for training stability and to preserve a "global" anatomical structure. This stage yields coarse reconstructions which could be used for estimating overall vertebral geometry in scenarios such as burst fracture evaluations.

After this step, the high-resolution model f_{Hi} , working on 128^3 voxel patches at the original scan resolution, refines the output by merging the up sampled coarse prediction with the high-resolution input to improve detail in structures such as pedicle contours and cortical bone integrity. Full-volume reconstruction is achieved using a sliding-window approach to mitigate memory constraints. To promote anatomical plausibility, including bilateral symmetry, a sagittal mirrored version of the defective input is added in the low-resolution step, thereby encoding the symmetry-aware features through the U-Net skip connections and convolution layers.

The model was trained on 150 synthetic vertebrae with approximately 600 total defect instances and tested on 20 vertebrae. In addition, 12 pieces of real-patient vertebrae that had reconstructions designed by an expert were used for external validation. The metrics for evaluation of all algorithms include the Dice coefficient, surface distance error, and new reconstructions score that is vertebral-centric and has clinical relevance. This architecture yields relative stability and anatomically correct reconstruction of many types of vertebral defects, creating a foundation for implementing deep learning for spinal implants in future works.

5.3 Implant Design and 3D Printing Workflow

After spine reconstruction, the anatomical models are encapsulated in a pipeline for designing and manufacturing patient specific spinal implants. The models of the reconstructed volumes are imported into Mimics (Materialize) software and using appropriate segmentation thresholds, bone and the reconstructed vertebral structure are isolated in the models. The segmented models are transferred to 3-Matic, where the clinicians can develop designs for uniquely personalized implants, based on their clinical needs. The implants can include vertebral body replacement cages, pedicle screw integration platforms, or lateral stabilization plates. The final designs were exported as STL files, which is the standard file extension for 3D printing. The implants are manufactured using fused filament fabrication (FFF) of a medical grade polyetheretherketone (PEEK), which is biocompatible and mechanically sound, for load-bearing orthopedic devices. The strength of this workflow allows the construction of spinal implants rapidly and with anatomically matched dimensions specific to individual patients.

5.4 Model Performance and Clinical Validation

The utility of the reconstruction system was demonstrated for synthetic and real patient datasets. On the synthetic test set the model demonstrated consistent submillimeter surface error (<1 mm) for standard and complex problems (e.g. loss of the full vertebral body). In clinical validation we produced models that achieved an average surface deviation of less than 1.2 mm from the original 12 patients. The reconstructions were independently and subjectively reviewed by spinal surgeons in which 10 of the 12 models were rated as "clinically acceptable," demonstrating the potential for useful models in practice. Moving forward we hope to continue by incorporating different and more diverse clinical CT images, as well as pursue cadaveric or prospective human trials. The next steps are important for not only assessing the anatomical accuracy of our reconstructions, but also assessment of useful implant fit, biomechanical stability, and surgical usability. Overall, this method delineates a complete end-to-end workflow (CT imaging, AI-based modeling, and 3D printing for patient-specific spinal implants) that moves the ball forward in terms of making precise spinal surgery a reality in today's world clinics.

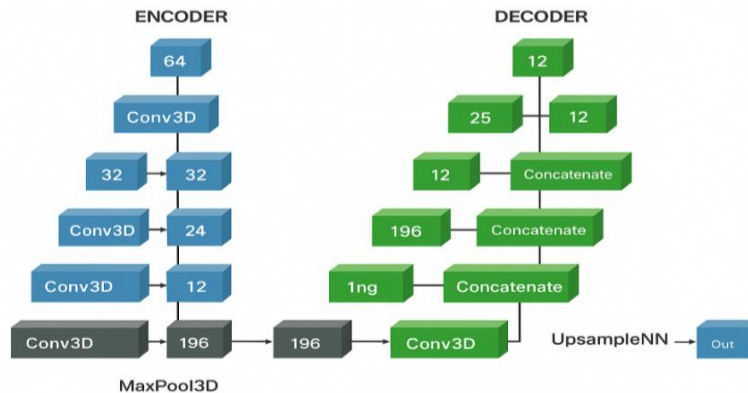


Figure 1: 3D CNN Architecture for Low-Resolution Input (64^3). For High-Resolution Input (128^3), Deeper Layers are Followed by a Final Bottleneck Tensor of 384 Channels at the end. For Symmetry with the 3D CNN, Sagittally Mirrored Input was Provided

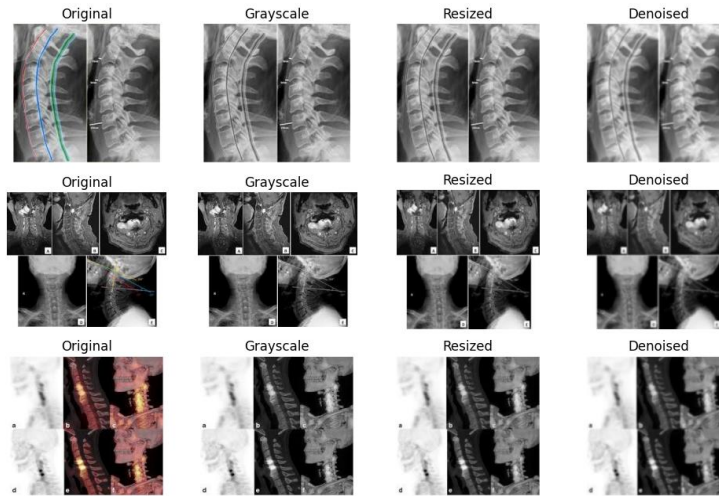


Figure 2: Select Reconstructions when Defects to the Thoracic, Lumbar, Bilateral, and random vertebrae Defects were Tolerated. In the Figure the Top Outputs are Error Maps, the Second are Defective Vertebral Inputs, and the Last Row are Reconstructed Outputs. The images demonstrate Sub-Millimeter Errors for the Majority of Samples

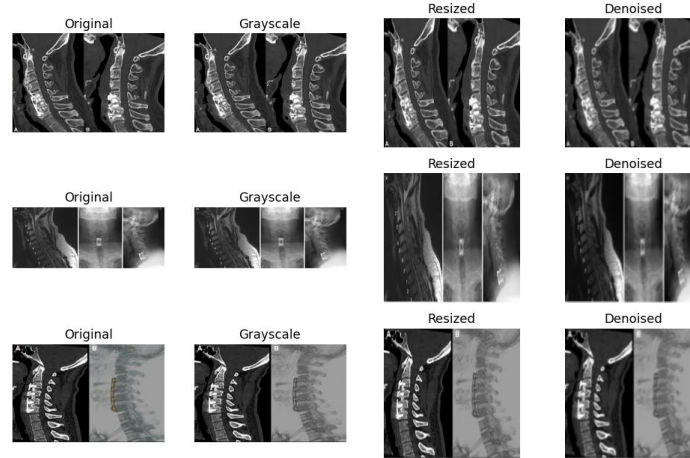


Figure 3: Original Vertebral Anatomy and Defective Inputs and Outputs of the Linear Latent Space Interpolation. The Center Regions are Being Recreated Accurately, while the Transitions at the Edges would Require Clinical Refinement

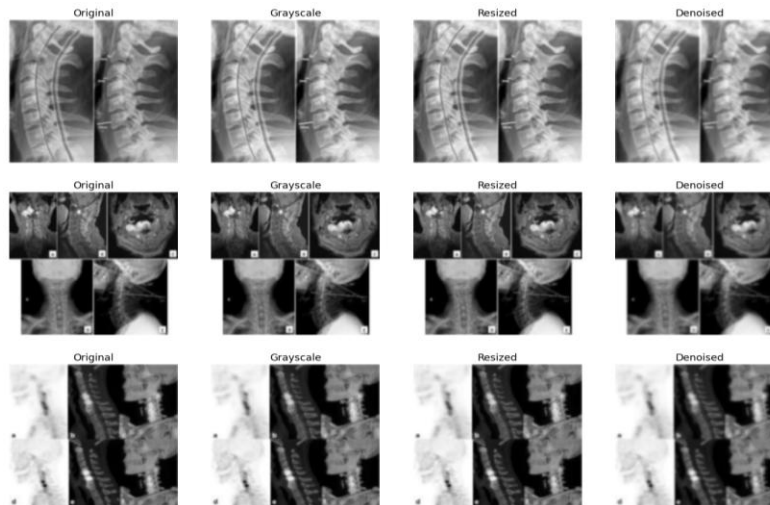


Figure 4: Real Clinical Reconstructions. There is Minor Disparity Remaining (though Primarily in the Multi-level Defect cases); However, these Real Reconstructions Demonstrate a high level of Anatomical Fidelity with a Mean Surface Reconstruction Error of less than 1 mm

5.5 Auto Implant Method

The Auto-Implant Method in AI-guided precision CT imaging exemplifies state-of-the-art spine restoration in anatomical and aesthetic fidelity. The Auto-Implant Method is a multi-branch design that predicts both the spine patch and the PEEK (polyetheretherketone) implant contour simultaneously. By designing these two entities projected on the same anatomical structure, it has a better chance of optimizing anatomical fit and cosmetic symmetry.

A unique design feature is the use of Gaussian curvature that is not only used for design principles but also governs the surface to provide the best fit and cosmetic appearance. The curvature-sensitive framework helps in ensuring that the final implant, while protecting and restoring the pre-operative spine contour, is commensurate with clinical and patient expectations. This is particularly important following craniectomy and where precise anatomical fit is paramount for neurologic safety, and facial symmetry. The incomplete area of the spine and the complete contour of the custom implant are predicted using a multi-branch neural network.

This method has used a cascaded CNN model which was created for the MICCAI 2020 Auto implant Challenge and had changed based on the spine Break dataset. The method started with landmark based spine alignment with rigid transformations which is the position of the anatomical centers, commonly this was the bilateral position for the auditory meatus and supraorbital notches. Following this step the method used a double network CNN in which the first network produced a low-resolution global volume reconstruction, while the second produced higher resolution patches to provide detail of the fine anatomy. In the system to assess the appropriateness of the reconstruction several metrics were used: surface distance metrics were used to identify geometric deviation, Dice coefficients were used to measure volumetric overlaps, and Gaussian curvature error was used to reflect on smoothness and aesthetic congruence. The performance measures described above together provide evidence of the clinical relevance and robustness for the reconstruction method and reason to consider using this method in surgical applications.

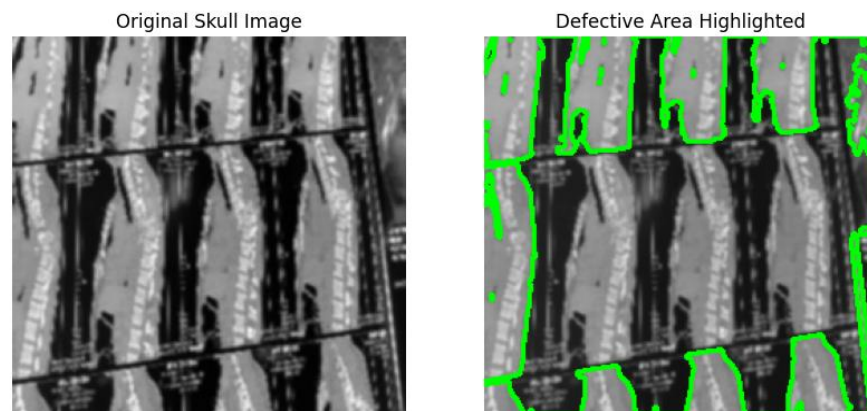


Figure 5: Figure Presented this Entire Procedure in Detail from the Input CT scan (a), The Detection of the Landmarks (b), The Alignment (c), The Reconstruction of the Implant (d), The Post-Processing (e), And Finally Changing the Coordinates (f). This Complete Workflow, which is best suited for 3D Printing a Biocompatible PEEK Implant, Contributes to the Advancement of Patient Specific Cranial Implants. With Adequate Strength of the Material And the structural Similarity to Cortical Bone, PEEK is an Optimal Candidate for Long Term Implantation. AI Assisted Implant Reconstruction Not Only Serves to Provide Functional Protection but Restores the Appearance of the Spine Producing a Notable Improvement to the Complete Outcome and Patient Satisfaction Related to Spinal Cord Repair

5.6 Shape Post-Processing

The Shape Post Processing phase is the process of modifying the AI generated spinal implant to remove defects and achieve anatomical accuracy. It is an important step prior to 3D printing the PEEK implant for surgical application. Noise artifacts are first removed, such as small spikes and disconnected pieces, using connected component analysis and morphological operations. Connected components analysis and morphological operations remove small noise pieces by examining the coordinates of the largest connected structure, which is the true implant shape, and removing any noise around it.

In order to enhance both structural fidelity and anatomical detail, a two-stage morphological approach is employed. The first stage uses morphological opening to leave none of the unnecessary extensions but has the consequence of potentially detracting from delicate detail at the defect boundary. The second stage uses the dilated mask of the morphologically opened shape to refine the original shape; this means still using the extra detail from the original feature to eliminate any irregular areas, while at the same time preserving the important anatomical details. As we can see in Fig.

6, this process preserves the integrity of the implant's boundary while only removing unwanted extensions. We have also applied landmark detection to improve the precision of reconstructions. A CNN trained on the 50 volumes of spine achieves very accurate automatic detection of auditory meatus and supraorbital notches at an average error rate of only 1.22 ± 0.70 mm and 1.84 ± 1.03 mm, respectively, providing useful landmarks to maintain consistent alignment of the spine, especially when positioning an implant. Our CNN based reconstruction model is trained on both synthetic datasets (i.e., spinal Break) and real patient CT scans with data augmentation to represent a variety of defect types and anatomical variations.

Reconstruction is completed in a cascaded approach, using a low-resolution CNN to map shape first, followed by a high-resolution CNN for fine detail. The combined approach enables strong generalization for multiple spine shapes and defective geometries. Performance was reported via the Dice coefficient (Dice scores of 0.903 in cases), and surface distance measures. Performance across collections were reported in Figure 7, where one additional test set is colored red for failing reconstruction.

In relation to the various defect typed (note proximal fracture defect), the fronto-orbital area looks like it is still somewhat coding complex, but the model has been able to replicate reconstruction and then reliably translate spine geometry to custom implant design has proven its clinical utility for spinal reconstruction. With AI performance accuracy, computational post processing and actual 3D printable PEEK, creates a solid pipeline for producing individualized surgical implants that are highly compliant and effective.

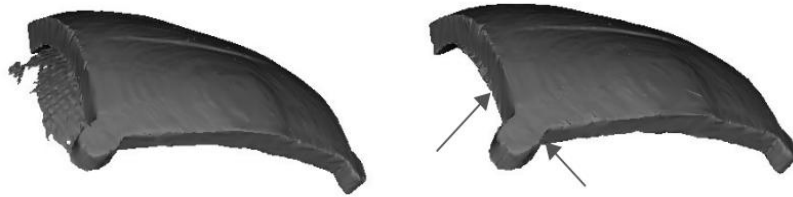


Figure 6: This Figure Describes Detail Preserving Morphological Post Processing to the Post Estimation Missing Shape, notice how the Unwanted Protuberance has been Removed and all the fine details Along the Edges of the Object have been Preserved

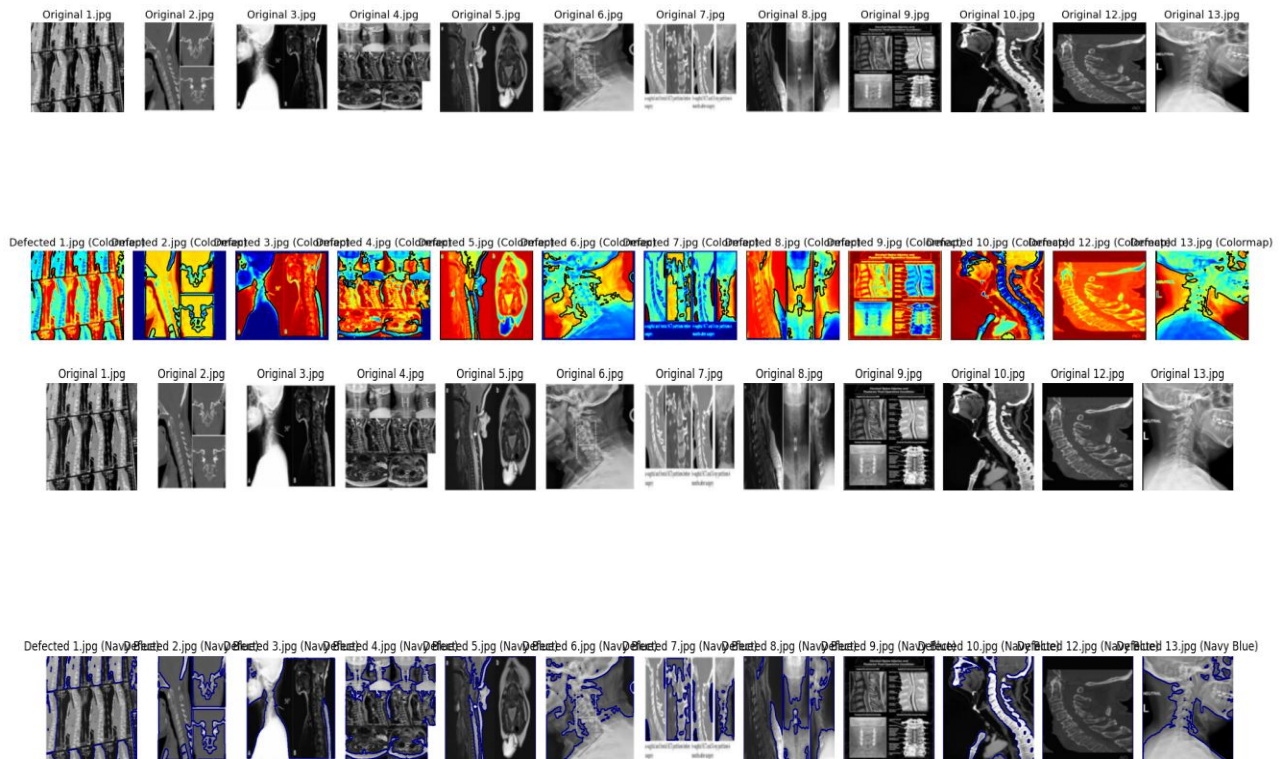


Figure 7: Here are Experimental Reconstruction Results Shown. The Rows Show the Standard Test Set, the Additional Test Set, And the Augmented Validation Data from Top to Bottom. The Last Example in the additional test Set shows a Reconstruction Failure, Indicated by the Red Highlight



Figure 8: Experimental Results of Reconstruction of Pre- and Post-Surgery Implant

Table 1: Analysis of Pre Surgery Image Post Surgery Image Defect Area (Pre) Defect Area (Post) Configuration Accuracy

	Pre-Surgery Image	Post-Surgery Image	Defect Area (Pre)	Defect Area (Post)	Configuration Accuracy
0	img_1.jpg	img_12.jpg	20	31	Config XYZ 95%
1	img_2.jpg	img_13.jpg	12	40	Config XYZ 95%
2	img_3.jpg	img_14.jpg	5	24	Config XYZ 95%
3	img_4.jpg	img_11.jpg	23	27	Config XYZ 95%
4	img_4.jpg	img_15.jpg	9	19	Config XYZ 95%
5	img_5.jpg	img_16.jpg	29	22	Config XYZ 95%
6	img_6.jpg	img_17.jpg	28	2	Config XYZ 95%
7	img_7.jpg	img_18.jpg	13	29	Config XYZ 95%
8	img_8.jpg	img_19.jpg	1	65	Config XYZ 95%
9	img_9.jpg	img_20.jpg	10	38	Config XYZ 95%
10	img_10.jpg	img_21.jpg	1	5	Config XYZ 95%
11	img_11.jpg	img_22.jpg	26	48	Config XYZ 95%

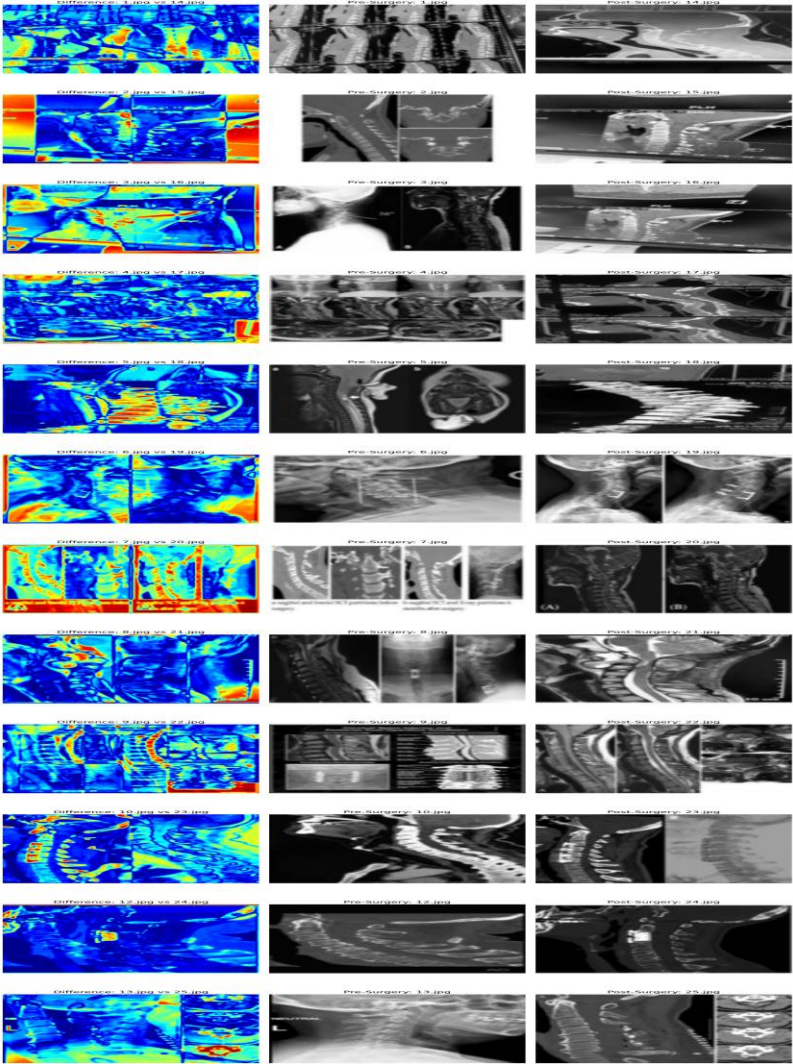


Figure 9: Difference Between Pre- and Post-Spine Surgery Results

6. Discussion

This research has shown the potential and clinical utility of an AI based, specifically a cascaded 3D CNN architecture, for spine reconstruction, using both simulated and clinical CT imaging datasets. The research aligns with the purpose of producing anatomically accurate and patient specific PEEK implant displays from volumetric CT data based on the need for spinal implants that are clinically passable as well as structurally and aesthetically appropriate. The major issue noted by previous authors regarding CNN based spine reconstruction is similar reliance on synthetic datasets when there is

insufficient anatomical variability in the dataset. Based on the findings of our study, we confirmed the issue, but our study progressed the debate by thoroughly testing the transferability of models created with synthetic datasets to clinical scenarios. Our study showed that while the synthetic datasets were "clean" and "uniform" they did not capture the detail of the irregularities or complex nature of real spinal defects. Especially with regards to the defect shape and border irregularity, this was demonstrated using Gaussian curvature analysis. These issues led to reconstruction artifacts and poorer surface smoothness in clinical applications than in simulations, demonstrating the potential limitations of being trained on synthetic data alone.

To address these limitations, we established a multi-branch cascaded CNN which validated on a combination of synthetic and clinical datasets. The model utilized a two-stage process in which it performed a global coarse reconstruction, through a low-resolution CNN (HR volume based on coarse reconstruction), and then enhanced the global reconstruction with fine details through a high-resolution CNN. An important innovation we made in the multi branch CNN was when using input volumes that were sagittally mirrored. This is especially important for Craniofacial osseous frameworks, and local regions around structures such as the orbits and frontal bone, where the accuracy of maintaining bilateral symmetry of the facial features is critical.

The data validated, which combined synthetic and clinical 3d datasets, suggested improved reconstruction accuracy, as well as generalizability. Although our results showed slightly higher surface errors than other studies that have used synthetic datasets, this was not unexpected as our test data included defect areas that had larger size and complexity around the anatomical borders. Nonetheless, the model achieved sub-millimeter surface error, which suggested model utility in clinical reconstructions.

Simultaneously, we proposed a new auto-implant design process that reconstructs the missing spine patch and also generates 3D-printable PEEK implant shapes, all in a single workflow. Curvature analysis was included within the design process to automatically correct asymmetrical geometries that could detrimentally affect clinical outcomes. The idea of accomplishing dual functions reconstruction and design will allow us to change the paradigm for fully automated modeling of cranial implants.

Moreover, the AI system allows for a transition from a traditional workflow that often requires significant human labour to an automated and reproducible workflow. Our AI model enables PSI workflows to shift to an accessible pathway to high quality reconstruction (reproducibility and reliability and scalable pipeline) compared to typical PSI workflows that rely totally on adept clinicians. While achieving final verification and intraoperative fit will still require clinical oversight, this workflow reduces planning time and support needed from the expert operators.

In conclusion, the project has a clear mandate to produce inexpensive, well-curated datasets. The synthetic cranioplasty dataset we released is based on CT scans from the National Medical Center that are anonymized and should help to plug the reproducibility gap and allow people to start doing research in a wider sense. The dataset provided is oriented to the Frankfort horizontal plane, maintains real defect complexity, providing a fairly definitive point of reference for future models to have an ability to benchmark against. However, there are limitations. Our model relied on a small clinical dataset for validation, with only nine patients. More studies need to be undertaken on larger population studies, and through different imaging modalities to ensure that it is robust. Our reconstruction project did poorly for locations closer to highly asymmetric bone structures or bone structures that had highly degrade. Perhaps with hybridized approaches that integrate biomechanical modelling we will be able to incorporate aspects regarding the original reconstruction location? Either way, this project adds a significant contribution, within the realm of spinal reconstruction automation, and is a solid foundation to ensure clinical translation and collaborate interdisciplinarity in the future.

7. Conclusion

The findings of this study reveal the ability for AI powered CT imaging to disrupt the design and manufacturing of 3D printed PEEK implants for spine reconstruction. By taking down significant pickup points in the traditional workflow specifically, manual, image segmentation of the spine reconstruction of the model, we built and assessed deep learning models to create a disintermediate cranioplasty design pipeline. The resulting benefits are less manual effort, better anatomical fidelity, and an increase in supply of patient specific high-quality implants. The Cut CNN segmentation method had clear benefits both clinically and practically with significantly better processing times than any existing manual tools. The automated reconstruction methods also performed well when benchmarked against existing manual tools and scored positively with expert assessment. There are clear evidence and value in AI based approaches in terms of converting methodologies into usable clinical design/implant workflows, called clinically either proving or validating.

The contributions of this study include the spine Break dataset, a novel benchmark dataset to evaluate the proposed methods, and new metrics of evaluation like Gaussian Curvature Error, that are more closely tailored by means of anatomical fidelity of the reconstruction. The initial studies into generative modeling for generated shape hypothesis suggest there will be increased progress towards individualized implants. In the future, it will be critical to continue to develop automated

ways with influence from clinical experts and participatory design input. The use of Artificial Intelligence with directed perspective of the expert clinical evaluators will be paramount to develop a tool that is scalable from the research lab to surgery practice, with the aim to assist in the goals of precision medicine to bridge the limitations in cranial reconstruction.

8. Potential Challenges and Future Work

Despite the advancements demonstrated, there are challenges and further prospects for improvement in developing AI based spinal reconstruction systems most importantly those that use 3D printed PEEK implants. The first need is for a larger training dataset that includes a wider variety of defect types and anatomical diversities. Increased variation will increase the robustness of the model and increase usability for clinicians across a variety of cases. Another area for additional development is in relation to user interactivity. While it would be impossible to engage a clinician in manual design for the entirety of the design process, there exists an opportunity to give a clinician a manual option through a friendly interface to amend implant geometries after surface prediction, or perhaps the clinician can incorporate their experience into the final implant after it was processed by the machine learning platform. Hybrid workflows can increase trust and usability in the clinic. In addition, in order to provide clinical validation to advance from proof-of-concept to clinical acceptance, clinical application in the surgical theatre is required. Structured clinical trials measuring safety, fit, and intraoperative performance of AI developed implants are required to satisfy regulatory obligations and to successfully address the concerns of surgeons and patients. Overall, this work lays a strong technical and conceptual foundation for integrating artificial intelligence into spinal model reconstruction. Through innovations in anatomical modeling, implant design automation, and AI clinician synergy, this approach offers a promising pathway to enhance the precision, personalization, and efficiency of cranial surgery.

9. References

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