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Original Research Article

Additive manufacturing of bespoke laminar plates for robotic spinal surgery

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Abstract: This paper introduces a novel methodology that utilises rapid prototyping and collaborative robotics to enhance spinal surgeries. The proposed approach enables the quick fabrication of customised laminar plates for vertebrae through Stereolithography (SLA) 3D printing, employing the biocompatible BioMed Photopolymer resin (USP Class IV). The methodology utilised involves converting Digital Imaging and Communications in Medicine (DICOM) format files or point cloud 3D data from 3D scanning into standard tessellation format (STL). This data is then utilized for reverse engineering and CAD modelling of the required laminar plate. The resulting plate is structurally unique and serves as a datum jig for the precise placement of posterior pedicle screws, ensuring accurate screw trajectory compared to the traditional free-hand technique.

I. Introduction

Spinal surgery plays a crucial role in treating a wide range of spinal disorders, including degenerative diseases, trauma, and deformities. One significant challenge in spinal surgery is the need for precise implant placement, particularly in cases involving pedicle screws. Accurate screw trajectory is essential to ensure successful fusion, stability, and improved patient outcomes.

Traditional free-hand techniques for screw insertion are often prone to human error, resulting in suboptimal placement and potential complications [1]. This is aggravated by the significant motion occurring in the lumbar vertebral bodies during a spinal surgery. A peak-to-peak motion of 1.3 mm [2] is observed due to patient breathing alone. Moreover, surgeon-induced motion can be up to 10 times greater.

Several techniques have been developed to increase the ease and accuracy of pedicle screw placement but often these require complex bespoke guides too. Common techniques currently used include the use of intraoperative fluoroscopy, intraoperative Computerized Tomography (CT), and image-assisted navigation [3].

To address these challenges, additive manufacturing technologies [4] and collaborative robotics [5] have emerged as promising tools in the field of spinal surgery. Additive manufacturing, also known as 3D printing, allows for the rapid prototyping of patient-specific anatomical structures and implants [6], enabling personalized treatment approaches. Among the various additive manufacturing techniques, Stereolithography (SLA) 3D printing has gained significant attention due to its high resolution, accuracy, and ability to produce complex geometries [7].

Due to the wide range of potential applications for 3D Printing, there has been a significant increase in interest in the application of 3D printing in the medical domain, similarly this is also the case with the digital design pathway whereby tools such as 3D scanning and 3D printing are implemented as core features with the design process whereby a wide range of tools are used for medical imaging, segmentation and anatomical analysis, planning, procedure design, amongst others. Early adopters have been found in oral and maxillofacial surgery as well as orthopaedic surgery [8].

Furthermore, researchers have explored the combination of biomaterials with organic tissues in 3D printing, demonstrating the generation and transplantation of various tissues such as skin, vascular tissue, cardiac tissue, and tracheal splints [9]. The progress of this technology has sparked a growing interest in its utilisation in spine surgery, with approximately 8% of related literature on rapid prototyping specifically focusing on its implementation in this field [10].

The potential uses of 3D printing in medicine encompass several areas including the development of patient-specific models for educational or pre-operative planning purposes, the optimization of the structure of readily available implants, the creation of customized jigs or guides to enhance the placement of instruments [11] and the production of instruments or implants tailored to meet specific patient needs or goals [12].

3D printed guide plates have shown to significantly lower the fluoroscopy times for each pedicle screw placement [13] from 1.2±0.7 minutes to 0.5±0.4 minutes ($p<0.05$). Some other studies [14] also reported reduced operation time and fluoroscopic frequency.

In 2018 Tan et al. [15] reported no significant improvements in the accuracy of the pedicle screw placement using 3D model assisted versus freehand technique (Accurately placed screws: 494/513 when 3D model-assisted vs. 339/352 freehand). This lack of improvement can be attributed to the considerable movement of the patient's spine during the surgical procedure, for which no effective compensation method exists.

Collaborative robots, also known as cobots, have emerged as a promising technology in various surgical fields, including spinal surgery [16]. Cobots are equipped with advanced sensors, actuators, and intelligent control systems that enable them to perform tasks with a high level of accuracy and repeatability. There are a growing number of suppliers of collaborative robots such as Universal Robots, ABB, ReThink Robotics, Kuka, Kawasaki, Omron, Epson, Mitsubishi Electric, FANUC, amongst others, many of which are now investing in the development of co-robotic solutions for the MedTech sector.

Bertelsen et al. [17] demonstrated improvement in pre-planned pedicle screw trajectories for spinal surgeries when a mechanical attachment is used for monitoring movement in the patient. Molliqaj et al. [18] also found that robot-guided pedicle screw placement is a safe, useful, and potentially more accurate alternative to the conventional freehand technique for the placement of thoracolumbar spinal instrumentation.

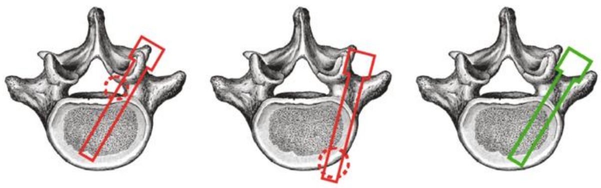

Figure 1: Schematic of screw insertion. A misplaced screw can breach the spinal canal producing nerve damage (left) or breach the outer vertebral walls damaging surrounding blood vessels (centre). A correctly placed screw should pass through the axis of the pedicle and be firmly anchored on the cortical bone (right).

The integration of collaborative robotics in conjunction with additive manufacturing holds promise for further enhancing the accuracy and efficiency of spinal surgeries. The use of cobots in a spinal surgery can significantly contribute to the placement of pedicle screws, which is a critical step in spinal fusion procedures.

The accuracy of pedicle screw insertion (Fig. 1.) is crucial for minimizing postoperative complications. Cobots can assist surgeons in precisely guiding the pedicle screws according to preoperative planning data, ensuring optimal screw trajectory and reducing the risk of malpositioning.

This paper introduces a novel approach that combines additive manufacturing and robotics to address the impact of spinal movements during pedicle screw placement. By tracking both minor and major movements of the spine in real-time, this methodology enables effective compensation, resulting in nearly 100% accurate pedicle screw trajectories. A proof-of-concept demonstration of this methodology was performed and is presented in this paper.

II. Material and methods

The proposed methodology leverages advanced imaging techniques, reverse engineering (Fig. 2), and CAD modelling to produce structurally unique laminar plates. The utilisation of these customised plates as jigs for prosterial pedicle screw implantation results in improved screw trajectory accuracy compared to traditional free-hand techniques and this accuracy can be further improved if cobots are used in combination to compensate for any movements during surgery.

This section is divided into four sub-sections:

1) Delineating the 3D data acquisition.
2) Reverse engineering.
3) Additive manufacturing.
4) Collaborative robotics.

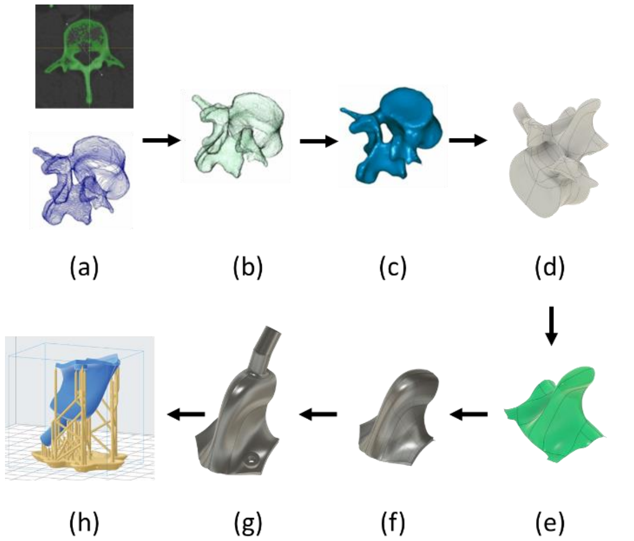

Figure 2: Process of laminar plate development; (a) CT Contour Detection and Segmentation of patient's DICOM data .dcm, (b) Point cloud (converted from .dcm or obtained by 3D Scanning), (c) Exported mesh (.stl), (d) Conversion to CAD, (e) Surface extraction, (f) Developed laminar plate, (g) Screw trajectory holes as drill jig , (h) Sliced file in Formlabs BioMed Amber Photopolymer Resin.

II.I. Patient Specific 3D Data Acquisition

This is a crucial step in the proposed methodology. Advanced imaging techniques, such as CT scanning or 3D scanning, are employed to obtain accurate anatomical data of the patient's spine. CT scanning provides detailed cross-sectional images, while 3D scanning generates a point cloud representation of the patient's vertebrae. These imaging techniques capture intricate details necessary for creating patient-specific models and surgical guides [19].

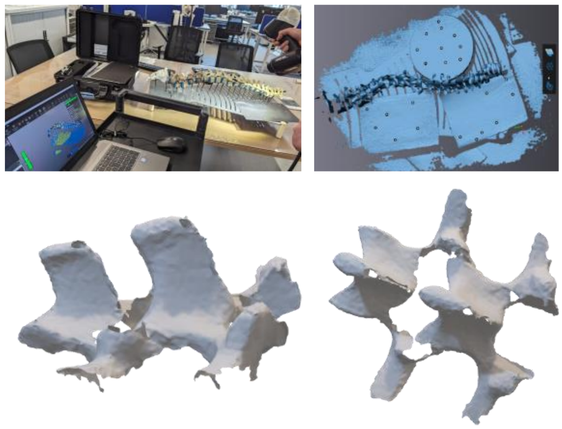

Figure 3: Top Left: 3D scanning using 'CREAFORM- Go! Scan 3D' structured light 3D scanner, Top Right: Aligned captured frames, Bottom Right and Left: Segmented RAW Point-cloud.

In CT scanning, a series of X-ray images are acquired, and specialized software reconstructs them into a three-dimensional volume using segmentation and anatomical analysis processes. This volume is then segmented to isolate the specific vertebrae of interest. On the other hand, 3D scanning (Fig. 3) utilizes lasers or structured light to capture the surface geometry of the vertebrae, generating a point cloud that represents the patient's anatomy.

The acquired data, in the form of DICOM files from CT scanning or point cloud data from 3D scanning, is processed using dedicated software tools. The data is converted into a mesh file format, typically the standard tessellation language (STL) or the OBJ format. These mesh files serve as the foundation for subsequent steps in the methodology.

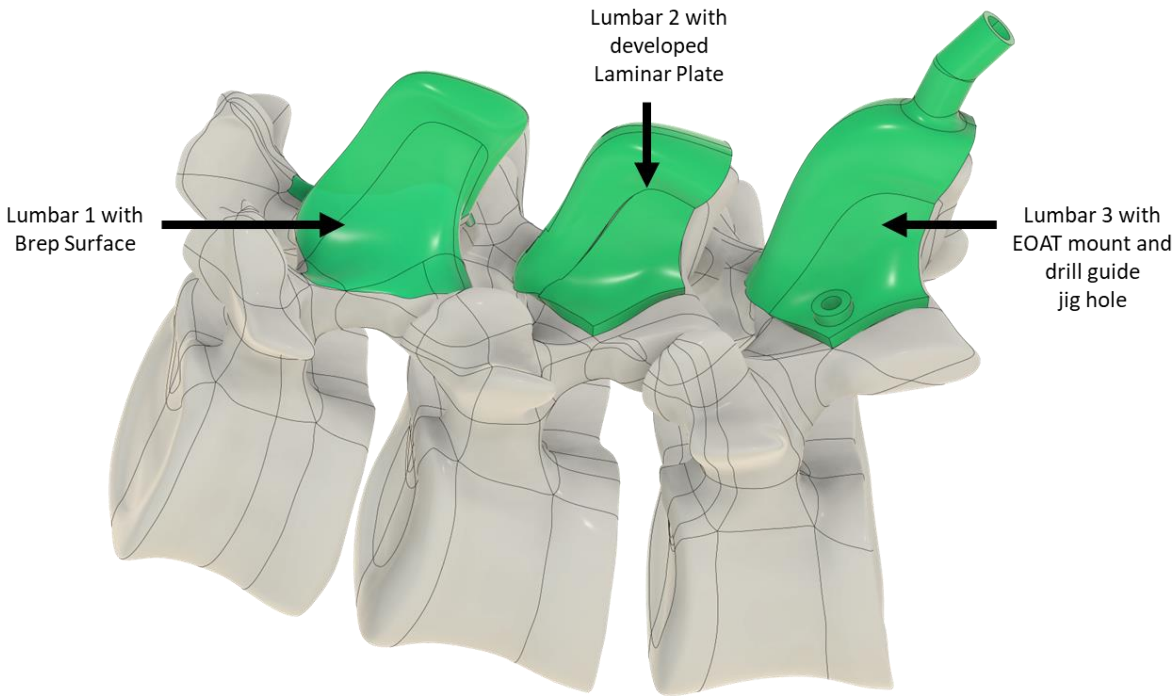

Figure 4: Development of laminar plates for specific (Lumbar) vertebrae.

II.II Reverse Engineering

Reverse engineering involves converting the mesh file obtained from the previous step into a Computer-Aided Design (CAD) model. Specialized software, such as Ansys SpaceClaim, Geomagic Design X or Materialize Magics, is utilized for this purpose. These software tools enable the manipulation and modification of the mesh file, allowing for precise modelling of the required laminar plates.

Using the CAD software, the specific design parameters such as drill trajectory requirements for laminar plates can be defined and optimised. This includes determining the optimal size, shape, and internal structures based on the patient's anatomical requirements and surgical goals. This is followed by either surface modelling to develop a fitting laminar plate or generative design to model the appropriate design. The CAD model (Fig. 4) serves as a digital representation of the laminar plates, ready for subsequent manufacturing steps.

II.III Additive Manufacturing

Additive manufacturing, specifically using Formlabs Stereolithography (SLA) 3D printing technology, is employed to rapidly fabricate the patient-specific laminar plates. SLA 3D printing offers high-resolution and excellent surface quality [20], making it suitable for producing intricate and structurally unique implants.

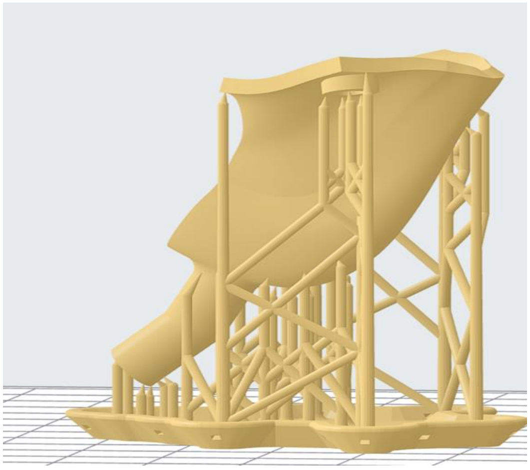

Figure 5: Pre-processing for 3D Printing (slicing in PreFrom software)

The biocompatible photopolymer resin, specifically formulated for medical applications, is chosen for the SLA 3D printing process. (Fig. 5) This resin meets the required biocompatibility standards, ensuring its suitability for surgical procedures in the human body. Known as BioMed Durable Resin, this 3D printing material is specifically intended for biocompatible applications that require resistance to impacts, shattering, and abrasion. With its classification as a USP Class VI material, it is suitable for use in applications involving long-term skin contact as well as short-term contact with tissues, bones, and dentin (less than 24 hours). The BioMed Durable Resin is manufactured in an FDA-registered facility that is certified under ISO 13485, further emphasizing its adherence to quality and regulatory standards.

The rapid prototyping capabilities of SLA 3D printing enable the efficient production of the customized laminar plates, minimizing lead time and allowing for iterative design improvements if necessary. The advantages of SLA 3D printing include its ability to produce complex geometries, excellent dimensional accuracy, and the availability of a wide range of biocompatible materials. These factors contribute to the precise fabrication of patient-specific laminar plates, enhancing surgical outcomes and improving patient comfort.

Furthermore, through pre-operative planning, additive manufacturing of realistic spinal training models is possible based on the collected data. Realistic spinal training model help with the planning of pedicle screw placement. In addition, 3D-printed molds of spinal disks and the spinal column can be produced followed by the subsequent silicone casting of the parts. Once assembled a realistic model provides surgeons with the opportunity to plan effectively the necessary delicate procedures.

II.IV Collaborative Robotics

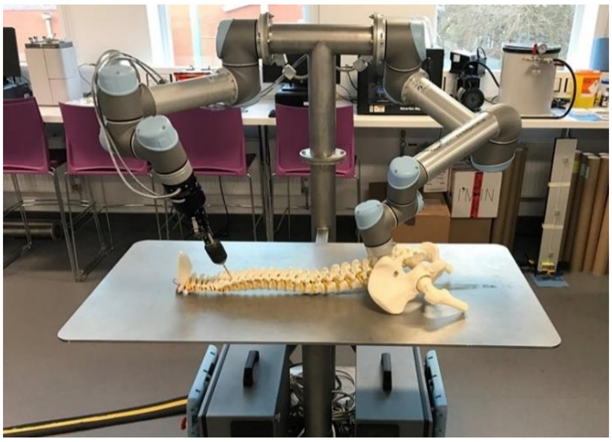

Figure 6: ScoliBot: collaborative robots for performing semi-autonomous surgical operations.

Collaborative robotics, or cobots, play a pivotal role in maintaining the accuracy of the drill trajectory during pedicle screw implantation.

ScoliBOT (Fig. 6) is a system that applies the use of two robots working in collaboration to perform semi-autonomous surgical operations. The first robot or “datum” robot is used to provide the system with a known point of reference within the real world. Consequently, the predefined offset from the datum position is used for evaluating the updated target world-frame coordinate for drilling position in near real-time (1 millisecond latency), using the frame transformations followed by inverse kinematics for the joint-space values. A pre-determined trajectory with real-time compensation is carried out by the second robot (tooling robot).

An advantage of this system is that it enables almost any point upon the bone to be selected to provide the known location upon the spine. This in turn allows for the bespoke requirements (e.g., abnormality and positioning) of the patient to be considered during the operation planning procedure.

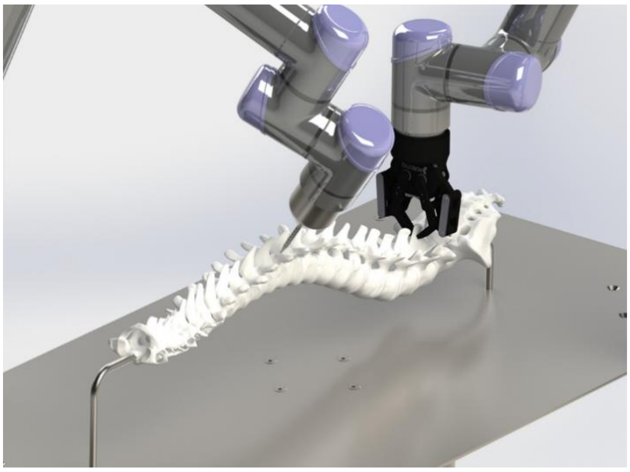

Figure 7: ScoliBot concept, gripper as datum.

Fig. 7 shows a finger gripper being used as a datum. This was used as a proof of concept and the inclusion of additive manufacturing enabled utilisation of vertebrae-specific custom laminar plates.

The developed pedicle drill guides serve as the End-of-Arm Tooling (EOAT) on one of the cobots, acting as a reference point for the surgical procedure. The cobot is securely mounted onto the patient's vertebrae of interest, enabling precise control and guidance. Operating in free drive mode with high compliance control, the cobot possesses the ability to adapt to the patient's movements and respond accordingly. This flexibility is essential in maintaining the proper drill trajectory throughout the surgical procedure. To ensure the accuracy of the screw placement, a force torque sensor, such as the Robotiq FT300 (Force-Torque sensor), is integrated into the End-of-Arm Tooling. This sensor precisely measures any forces exerted in the direction of motion.

The force-torque data captured by the sensor is then transmitted to a Unity-based digital twin in real-time. With an impressive latency of just 5 milliseconds, the cobot, in conjunction with the tool, reacts promptly to compensate for any motion in the patient's spine. This closed-loop system ensures that the drill maintains the desired trajectory, achieving a high level of accuracy and precision.

III. Discussion and Conclusion

The collaborative robotics approach provides numerous advantages in spinal surgery. By incorporating cobots into the procedure, surgeons can overcome challenges associated with human factors, such as hand tremors or fatigue. The cobots' high compliance allows them to work in close proximity to the surgeon and adapt to any unexpected movements, providing an additional layer of safety during the surgical process.

Moreover, collaborative robotics in spinal surgery offers the potential for improved surgical outcomes and reduced complications. The accurate and consistent drill trajectory achieved by the cobots enhances the stability and fusion success rate. It minimizes the risk of screw misplacement or damage to vital structures surrounding the vertebrae, ultimately improving patient safety and postoperative recovery.

The collaborative robotics approach in spinal surgery, coupled with the utilization of pedicle screw drill jigs, offers significant potential for improved surgical outcomes and reduced complications. The accurate and consistent drill trajectory achieved by the cobots enhances the stability and fusion success rate. By compensating for any motion in the patient's spine, cobots minimize the risk of screw misplacement or damage to vital structures surrounding the vertebrae, leading to improved patient safety and postoperative recovery.

One of the key advantages of incorporating 3D printing technology into spinal surgery is the rapid development of pedicle screw drill jigs that are bespoke to the patient. With the ability to directly translate patient-specific anatomical data into precise and customized designs, 3D printing enables the production of drill jigs that perfectly fit the vertebrae. This level of accuracy and tailored fit enhances the overall surgical procedure by providing surgeons with a reliable and consistent guide for screw placement.

Specifically, the use of Stereolithography (SLA) 3D printing in spinal surgery offers exceptional precision in terms of fitting the pedicle screw drill jigs onto the vertebrae. SLA technology utilizes biocompatible photopolymer resins that are specifically formulated for medical applications. This ensures patient safety and compliance with medical standards. The bio-compatible resin used in SLA 3D printing guarantees that the materials used for the drill jigs are safe for implantation in the human body, minimizing the risk of adverse reactions or complications.

Furthermore, SLA 3D printing enables the production of drill jigs with complex geometries and intricate internal structures. This capability allows for the incorporation of additional features, such as guide channels or alignment markers, which facilitate precise screw placement during surgery. The high resolution and excellent surface quality provided by SLA 3D printing contribute to the overall accuracy and reliability of the drill jigs, ensuring optimal surgical outcomes.

In conclusion, the integration of 3D printing technology, particularly SLA 3D printing, in spinal surgery enables the rapid development of patient-specific pedicle screw drill jigs. This approach ensures a tailored and precise fit on the patient's vertebrae, improving the accuracy and reliability of screw placement. The use of bio-compatible resin guarantees patient safety and compliance with medical standards. Incorporating 3D printing technology in spinal surgery provides surgeons with valuable tools for achieving optimal results, enhancing surgical outcomes, and ultimately improving patient safety and postoperative recovery.

Additionally, the bespoke pedicle drill guides used in this methodology offer the advantage of being replaceable on the datum robot, enabling quick swapping and drilling on another vertebrae. This flexibility allows for efficient and streamlined surgical procedures, reducing surgical time, and improving overall efficiency in the operating room.

IV. Future Scope

The proposed methodology for spinal surgery using collaborative robotics and custom pedicle drill jigs provides exciting possibilities for future advancements in the field. Imaging and optical techniques can be employed to tangibly measure trajectory accuracy, providing valuable feedback to further improve the closed-loop system.

Additionally, the integration of augmented reality (AR) technology holds great promise, enabling surgeons to observe the operation in real-time and monitor data during the drilling procedure. AR can provide surgeons with precise visual overlays and real-time feedback, allowing for minute adjustments in speed, feed rate, and other parameters. Furthermore, the incorporation of machine learning and artificial intelligence algorithms can optimize the collaborative robotics system by analysing patient data and surgical outcomes, leading to personalized and optimized surgical strategies. Robotics-assisted navigation systems, combined with advanced imaging, can enhance surgical accuracy by providing real-time tracking and precise instrument positioning.

Haptic feedback systems can also be integrated to provide surgeons with a sense of touch and force feedback during the procedure, improving their perception and control. In conclusion, the future scope of research in spinal surgery using the proposed methodology includes advancements in imaging and optical techniques, augmented reality, machine learning, robotics-assisted navigation, and haptic feedback systems. Continued exploration and development in these areas will undoubtedly contribute to the evolution of spinal surgery, providing surgeons with advanced tools and techniques for achieving optimal results, improving patient safety, and enhancing postoperative recovery.

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Author's statement

The authors state no conflict of interest. Informed consent has been obtained from all individuals included in this study.

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