Elsevier Editorial System(tm) for World Neurosurgery or its open access mirror
Manuscript Draft

Manuscript Number: WNS-19-4196

Title: Use of 3D printing technology in complex spine surgeries

Article Type: Original Articles

Keywords: spine tumor; 3D printing; custom made implants; pre-operative models; medical simulation; custom made tools; en bloc resection.

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Abstract: background- Medical implications of 3D printing technology have evolved and are increasingly used. Surgical spine oncology involves at times complex resection using various surgical approaches and unique spinal reconstruction. As high general complication rate including hardware failure is reported, carful pre-operative planning and optimized fixation techniques should be performed.
3D printing technology allows the improvement of pre-operative planning, practice and exploration of various surgical approaches, and designing customized surgical tools and patient specific implants.

Objective- Use of 3D printing technology in complex spine surgeries.

Methods- Between 2015-2018, all complex spine oncological cases were evaluated and assessed for the possible benefit of use of 3D printing technology. Following high quality imaging, a computerized integrated 3D model was created. Based on the planned procedure considering the various surgical steps, a customized 3D model was planned and printed, and in select cases a 3D custom made implant was designed and printed in various sizes with matching trials.

Results- A total of 7 cases were selected for the use of a 3D printing technology. For all, a custom-made model was created. In 3 of these cases a customized 3D printed implant was used. Special customized intraoperative instruments were made for 2 cases, and a simulated surgical approach was performed in 5 cases. In 2 cases, pre-bent rods were made based on the model created and were used in surgery later on.

Conclusions- For complex spine oncology cases the use of 3D printing allowed better pre-operative planning, simplified the operative procedure, and enabled improved reconstruction.

Use of 3D printing technology in complex spine surgeries

Authors' cover letter

Thank you for reviewing this paper.
It is our belief that it has an interesting and important massage to spine surgeons encountering and treating complex and challenging spinal oncological disease.
The data presented in this study, includes our experience in using 3D printing technology in these complex cases, where we believe it helped better our approach and overall success. Our experience gained using this technology could help fellow surgeons to optimize their approach and maximize the advantages of current 3D printing technology in complex spine cases.
Both data and conclusions presented in this paper have not been presented or published before.
I, Ran Lador, certify that this manuscript is a unique submission and is not being considered for publication, in part or in full, with any other source in any medium

Thank you again for considering this paper for publishing

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*Title Page

Use of 3D printing technology in complex spine surgeries

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Highest academic degree for all authors – Assistant professor.

Keywords –
spine tumor, 3D printing, custom made implants, pre-operative models, medical simulation, custom made tools, en bloc resection.

Short title –
Use of 3D printing technology in complex spine surgeries
No support was accepted for this manuscript.

Conflict of interest - none

No funding was received for this manuscript.

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Abbreviations –

1. 3D – three dimension
2. IRB – Institutional review board.
3. CT – computed tomography.
4. MRI – Magnetic resonance imaging.
5. PET-CT – Positron emission tomography- computed tomography.

Use of 3D printing technology in complex spine surgeries

Introduction

Three-dimensional printing technology has significantly evolved in recent years, more specifically, medical implications have developed and being increasingly used in various medical and surgical scenarios. The use of this technology for either the creation of anatomical models or customized implants is of great potential for bettering patient care. Medical printed modeling for both teaching purposes and clinical pre-interventional planning has gained popularity especially in complex medical situations where abnormal anatomy, certain anatomical surgical considerations and precise reconstructive procedures are required.

Surgical treatment of spine oncology cases involves at times complex resection. The surgical approach is limited by adjacent important anatomical structures as well as the inherent limitation of the neural elements. A carful pre-operative planning should therefore be made considering and addressing these issues while planning the surgical treatment based upon the accepted oncological principles.

Following the resection of the tumor, a reconstructive part of the surgery is required to enable the function and stability of the spine. A general complication rate of 30-60% is reported in these cases [1-3]. Of them, hardware failure rates are reported to be between 4-10% [1,3-5]. Rates are higher usually when the resection involves an irregular pattern, multilevel tumors, or areas of high mechanical demand such as lumbosacral, thoracolumbar, and craniocervical transitional zones.

For these select cases, customizing the implant, to perfectly fit the patients' anatomy might have an additive value, possibly reducing the rate of hardware failure.

The emergence and development of 3D printing technology allows the treating surgical team to improve their pre-operative planning, practice and explore various surgical approaches, and design customized surgical tools and patient specific implants.

A series of cases where three-dimensional printing technology was used in complex spine surgical procedures is described in this report.

<u>Materials and methods</u>

Between 2015-2018, all complex spine oncological cases were evaluated and assessed for the possible benefit of use of 3D printing technology. As this was an authorized use of approved medical technology – it was exempted from need of patient consent by the IRB. For these select cases, a high resolution thin sliced CT and contrast MRI were obtained. Added contrast CT angiography was done if the tumor was in proximity or the surgical approach might warrant dissection close to a major blood vessel.
A computerized 3D model was created using the GrabCAD software (Stratasys Ltd). This allowed the integration of all scans into one combined three-dimensional model that included the tumor with its surrounding tissue and bone, all major surrounding organs and important anatomical structures as well as the area of the planned surgical approach. Based on the planned surgical procedure considering the various surgical steps, a customized 3D model was planned and printed. The decision on exact material composites, transparency, color and flexibility was made based on the actual anatomical properties, the need to mobilize or dissect through various tissue and organs during surgery, and the need to visualize the tumor or important anatomical structures if embedded in a vertebra or other organ.

Following the printing of the model, the need for customized 3D titanium printed implants was determined. In general, the model was used for any number of the following –

- optimize surgical approach
- practice model for alternate approaches and trial of various instruments.
- assessment of the need and specifics of the implant that will be required in the reconstructive phase.
- Trial and modeling of implants sizes and configurations, as well as insertion methods and trajectories.
- The possible use of a customized printed operative instruments (JIGs) for precise osteotomies, protection of anatomical structure or for optimized cryotherapy needle placement.
- Pre-shape rods according to the model for optimized alignment.

In select cases where an implant would be required for replacement of a resected vertebrae, a 3D custom made implant was designed and printed using Titanium (Ti6Al4 V) printed technology (4WEB medical, Frisco, Texas). The design of the implant addressed several structural issues that could be customized for optimized mechanical support including -

- Customization by mapping the interface of the endplates to perfectly fit the superior and inferior remaining vertebrae.
- Determination of the required height, width, and angulation of the endplates to restore the patient's original anatomy in both coronal and sagital plains.
- The size of the implant in terms of axial dimensions was determined as a percent of the original replaced vertebrae.

For every case that required a customized 3D printed implant, several options were made in different percentage, height and angulation of the implants. These were selected based on the anticipated resection, with other implants printed to be used in case of wider/different resection than planned. These “backup” implants were usually in sizes above and below the anticipated implant and for two cases these varied in lordotic angle in case the amount of intraoperative correction would not meet the pre-operative plan. Furthermore, to improve the intraoperative implant selection following the resection, matching trial implants were printed and sterilized.

Results

Between 2015-2017, a total of 7 cases were selected for the use of a 3D printing technology. For all, a custom-made model was created. In 3 of these cases a customized 3D printed implants were used. Special customized intraoperative instruments (JIGs) were made for 2 cases, and a simulated surgical approach was performed in 5 cases. In 2 cases, pre-bent rods were made based on the model created and were used in surgery later on.

Case presentation –

Case 1

An 18-yr. old male, diagnosed with an L5 Giant cell tumor, treated initially with percutaneous fixation of L4-S1, and Denosumab (XGEVA). Due to tumor progression, a decision for complete vertebral resection was made.

3D printed model demonstrated the best approach to resect the tumor and insert an implant between the Iliac vessels (fig 1). Based on the model – a midline transperitoneal approach was selected.

A 3D printed implant was used for anatomical reconstruction. The original patient's sagital alignment characteristics were restored and the endplate interface was mapped.

Various implant sizes varying in the percentage and height of the implant were printed with matching trials (Fig. 2).

The implant was filled with allogenic bone graft and was inserted to its position with perfect fit (FIG 3).

Case 2

20-yr. old male with a suspected L4 osteoid osteoma. A minimal invasive resection was performed using a direct lateral approach. 4 months later a recurrence was demonstrated on follow up imaging (Fig 4). Due to its rapid progression and following a biopsy confirming a diagnosis of Osteoblastoma, a complete resection was planned. A 3D model was created for operative approach planning as well as to check the feasibility of using a cryoablation technique after tumor resection.

A custom-made Jig was planned and printed for optimized cryoablation needle placement, this served also as a protection of adjacent anatomical structures from thermal injury during the procedure. (Fig 5).

Case 3

56-yr. old female 5 years post lumpectomy due to localized breast carcinoma, diagnosed with an isolated localized spinal metastasis. For a planned enbloc resection a 3D model was created, demonstrating the adjacent anatomical structures including the kidneys and diaphragm. This was beneficial for planning the surgical resection and surgical approach. A customized Jig was printed to protect the dural sac during the use of a Diamond – threadwire Tomita saw in the surgical resection of the vertebra (Fig 6).

Case 4

A 63-yr. old male, 15-yr. post localized renal cell carcinoma resection. An isolated single thoracic metastasis was diagnosed Involving the RT. Cortex of the vertebral body, pedicle and proximal rib. In order to preserve the vertebral body an en bloc resection involving partial vertebrectomy was planned. To explore the feasibility of an all posterior resection, a 3D model was printed. The surgical procedure was modeled, demonstrating that such a resection would not be possible without either endangering the spinal cord or invading the tumor. following the simulation, a combined anterior and posterior approaches were planned, and re-simulated (Fig 7).

Case 5

A 13-yr. old female diagnosed with Ewing sarcoma involving the C3 vertebra. A 3D model that included the mandible, and major vascular structures was printed. A complete C3 resection was planned with the use of a 3D custom made implant that included a locking mechanism to the adjacent vertebrae. (Fig 8).

This implant was trialed on the model prior to surgery, for fit, screw trajectory and insertion technique (Fig 9).

Case 6

A 39-yr. old male, 5 years post 3 level en-block resection of Chondrosarcoma. The Mesh Titanium cage gradually subsided causing the posterior instrumentation to repeatedly fail. As the patient refused revision of the anterior column, multiple attempts were made to replace the posterior instrumentation using double rod techniques of both titanium and Cobalt-Chrome materials, all eventually failed due to inadequate anterior column support.
Lastly, the use of a novel Carbon-fiber system (CarboClear, LTD.) was made for its flexibility and lack of fatigue failure quantities. Carbon-Fiber rods are made using a specific mold in several standard pre-bent shapes. Bending these rods can only be made using extreme temperatures thus intra-operative bending is not possible. As none of the regular rods fitted both length and alignment of the patient, pre-bending of the rods was required. Using a 3D printed model as template, a tailored rod shape was made (Fig 10).
During surgery, the Carbon-Fiber system – using the pre-bent rods were placed with a perfect fit (Fig 11,12).

Case 7

A 17-yr. old male, 2 years post posterior decompression of a T3 aggressive hemangioma without instrumentation, suffering from tumor recurrence and local kyphotic deformity.
A combined procedure involving tumor resection and deformity correction was planned.

A 3D model was printed, tumor was removable to allow the modeling of resection and deformity correction. This enabled the planning of a replacement implant following deformity correction of the local kyphosis. The spinal cord was printed out of a relatively flexible material allowing simulation of the degree of deformity correction.

Custom made implants were printed in various sizes and kyphotic angels. The endplates of the implants were mapped according to the superior and inferior vertebrae. since the superior endplate of the inferior vertebra was significantly eroded, a mapped endplate of the implant allowed the proper and stable fixation of the implant (Fig 13). To that extent, no other "non-custom" implant available could lay stable on that deformed endplate.

Pre-bent rods were made according to the desired correction to be used as intra-operative templates and temporary stabilizers.

Discussion

When attempting to treat complex oncological spine pathologies one requires a thorough understanding of both the specific anatomy related to the disease, at times altered by the tumor or previous treatment attempts made, as well as the tumor's exact location and relations to the spine and its adjacent elements. This appreciation of tumor margins as well as structural anatomical limitation of the surgical approach is mandatory while planning to surgically treat these tumors.

Current imaging modalities including MRI, CT and PET-CT, provide a two-dimensional presentation of this three-dimensional complex problem.

While 3D computer reconstruction improved this presentation, with the introduction of 3D printing technology, the possibility to create an actual model of the pathology and the surrounding anatomical structures has emerged. This model, representing in a 1:1 scale the exact area of interest allows the surgeon to appreciate the pathology and most potential pitfalls in a planned resection prior to the operation, thus improve the preoperative planning. Furthermore, various attempts of simulations can be made on the model, reducing the chance of unexpected limitations and problems during surgery.

Anatomical modeling

Modeling the area on interest involves the appreciation of the tumor and its surroundings, as well as the area relevant to the surgical approach.

For this, different types of tissues require various types of material to be printed from. These vary in terms of flexibility, consistency, and transparency. Mimicking these qualities in a reasonable manner allows better appreciation of the limitations and possibilities in the surgical resection.

Having a transparent vertebra where an intravertebral part of the tumor can be visualized allows the surgeon to plan and simulate a precise and optimal osteotomy without jeopardizing the tumor's margins while enabling the most convenient surgical planes of resection.

Various different tissues have different consistency and flexibility. At times these are "used" for approaching the spine such as collapsing a lung or mobilizing the abdominal vascular structures. It is therefore important to present these qualities in a model, especially if a surgical approach or access area for instrumentation are in question.

According to the various steps of the procedure and surgical approach, models can be printed in several different pieces. These can simulate the planned steps of the surgical procedure.

Customization and Pre-shaping of rods

Pre-shaping of rods was performed in two of the cases. In both cases, the model was used as a template for the pre-bending. In one case, the pre-bending was performed for sagital alignment correction. The rods where bent according to the planned correction and were used intraoperatively as a reference for kyphotic angulation correction. This appeared to be very accurate and helpful tool during surgery. In the second case, a carbon-fiber system was planned for revision of fixation. As rods made of carbon-fiber cannot be bent intraoperatively, the pre-bending was performed based on the model at the manufacturer facility. In that case, having a model presenting the exact spinal alignment was tremendously important as the system used requires a precise matching of the rod to all screws.

Customization of surgical tools and jigs

Customized model allows for the planning of specific intraoperative tools that could improve the accuracy and safety of the procedure. In this series, customized tools were printed for spinal cord protection (while cutting through the disc using a Diamond – threadwire Tomita saw) and during cryoablation, where a customized tool was used to optimize needle placement while protecting important adjacent vascular structures from thermal injury. In future cases, customized tools could be made for optimized osteotomies for location and trajectory of the cuts, or any other intraoperative steps that might be considered during the pre-operative planning.

Customization of surgical implants

Titanium 3D printed implants provide both structural strength, while allowing space for bone substitute materials for improved bone ingrowth [6].

Unlike other implants available, the recreation of the sagital angulation (lordosis or kyphosis), potentially adds stability and reduces the chance of sagital malalignment. Furthermore, in cases where an un conventional area of contact exists, a customized mapping of the endplates or implant vertebrae interface creates a large stable area of contact adding to the stability of the implant. To that extent, in cases of significant shearing forces on the implant, such as the L5 vertebra in a patient with a large sacral slope, customized implant that maintains the patient's lumbar lordosis and sagital alignmen might decrease the chance of hardware failure.

The use of Titanium lattice structure creates significantly less radiologic interference when compared to other implants [7]. This allows better adjuvant radiation therapy and local disease recurrence monitoring. This structure also allows the implantation of bone substitutes increasing the chance of bone ingrowth and improving implant stability (Fig 3). Roughened Titanium surfaces have been reported to create a favorable osteogenic environment compared to both smoothed Titanium surfaces and PEEK [8]. Combining the large amount of bone substitute and roughened Titanium surface, possibly creates a favorable osteogenic environment, improving the chance of osteointegration and implant stability. Further long-term comparative studies are required to support this notion.

In one case the implant design included a locking screw mechanism. The specific angulations of these screws were calculated based on the computer and actual model of the patient (fig 9) allowing optimized purchase of the screws while considering the limitation of the angle of insertion. This locking method seemed to be advantageous for the stability of the implant similar to cervical intervertebral implants available. Anterior plate was added for extra protection, however in future cases this will probably could be avoided as the purchase of the cage alone seems to be stable enough.

Conclusion

3D printing technology is being increasingly used in medicine. In this series the use of this technology in complex spine oncology surgery is described.

For these select cases, the use of 3D printing allowed better pre-operative planning and simplified the operative procedure. Although the use of customized printed implant seemed to achieve stability, still larger series are needed to determine their value compared to other implants available.

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Figure legends -

Fig. 1 – 3D printed model of the lower lumbar spine and the sacrum (A-C). anterior view (A), Posterior view showing the previous percutaneous fixation (B), tumor and L5 vertebra removed – note the two pieces detached according to the planned surgical procedure (C). 3D computer reconstruction (D). intra-operative view of the anterior approach. Note the vascular and urethral structures (E).

Fig. 2 – Custom made Titanium implant. Filled with allogenic bone graft (A), lateral view restoring original lordotic angle (B), with a matching trial cage (C), multiple implants in various sizes and angles (D).

Fig. 3 – Post operative imaging – CT scan coronal (A) and sagital (B) reconstructions, note the bone ingrowth into the implant at both endplates. X-ray LAT (C) and AP (D).

Fig. 4 – CT images, initial presentation – suspected OO (A,D), following resection, tumor progression and suspected osteoblastoma (B,C).

Fig. 5 – 3D printed model – with the tumor before removal (A), after tumor intralesional resection (B), custom made tool for cryotherapy needle placement and anatomical structures protection mounted on the diseased vertebra (C), note the similarity between MR images and model (D,E).

Fig. 6 – 3D printed model – anterior view showing the diaphragm in yellow, renal veins and kidney in blue and renal arteries in red (A,B), after vertebral resection from posterior approach (C, D).

Fig. 7 – 3D printed model for surgical approach simulation (A), first attempt at all posterior approach – resection of the tumor without tumor violation or spinal cord jeopardize was not possible (B), second attempt at anterior and posterior combined approach (C), resected specimen (D).

Fig. 8 – 3D reconstruction and planed implant design (A,B) note the planed screw trajectory (yellow), 3D printed model posterior (C) and lateral (D), tumor and arteries (vertebral and carotid) in red, veins in blue, spinal cord in yellow.

Fig. 9 – follow up x-rays lateral (A) and AP (B).

Fig. 10 – 3D printed model of the spine and broken rods – posterior view (A), lateral view (B), with standard rods – note the mismatch between the rod and screws (C), after customized bending of carbon rods – note the matching of the pre-bent rods to the screws (D).

Fig. 11 – intraoperative and follow up imaging – intraoperative view of the carbon structure (A), follow up CT in sagital reconstruction showing rod curvature and fit to the screws (B), bony bridge formation along the rods white arrow (C).

Fig. 12 – comparison imaging between metal and carbon implants. CT reconstruction of metal implants Sagital (A) and axial (B), MRI axial imaging of metal implants (C). CT reconstruction of carbon implants – sagital (D) and axial (E), MRI axial images (F). note the reduced scattering on CT and better tumor assessment on MRI.

Fig. 13 – 3D printed model with the tumor (black) and implant options varied in size and kyphotic angle (A), model was flexible at the spinal cord to allow modeling of deformity correction (B), with trial implant AP (C) and LAT (D) – note the inferior endplate mismatch, with a custom made implant AP (E) and LAT (F) – note the inferior endplate matched to the vertebra.

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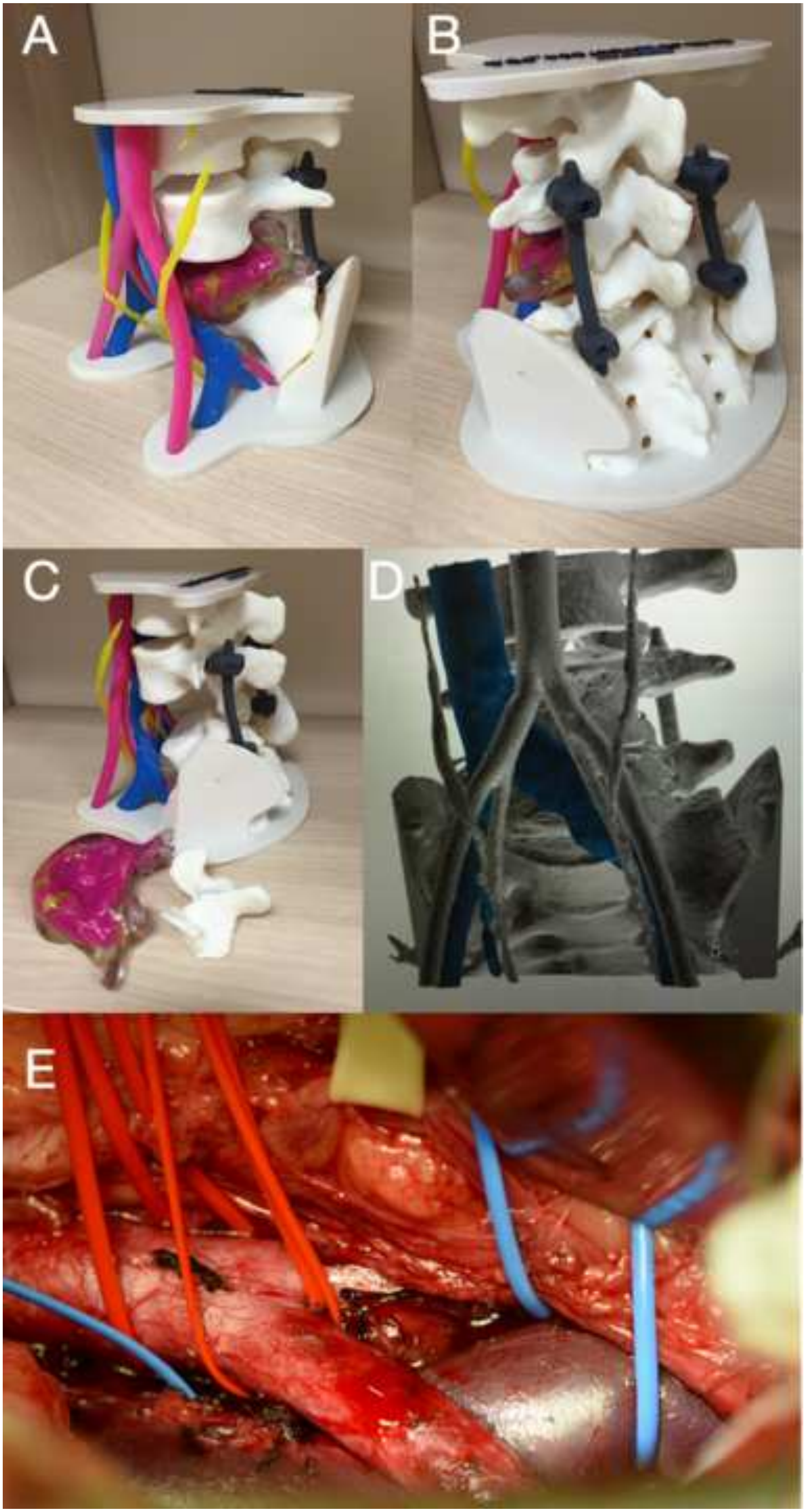

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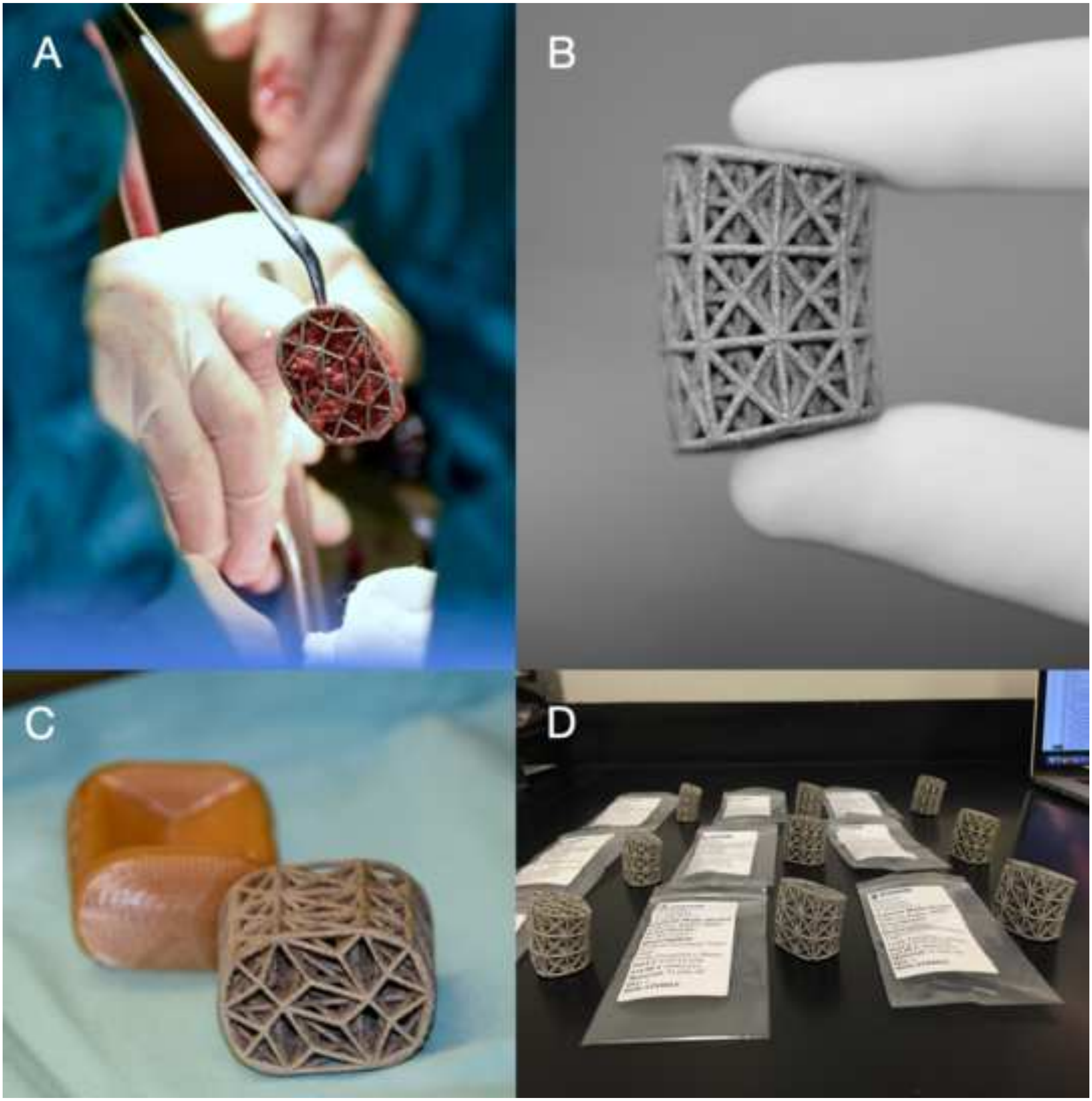

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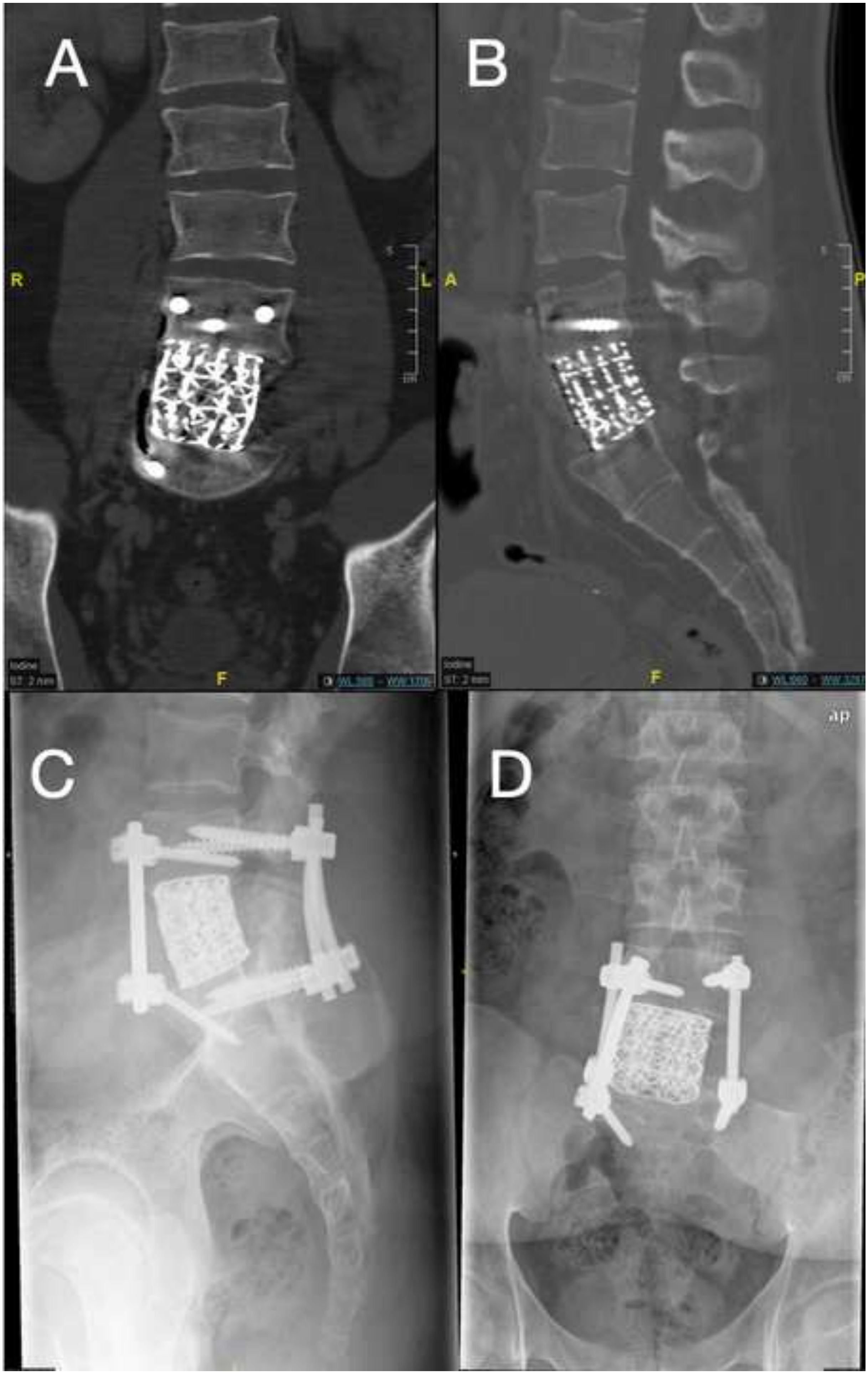

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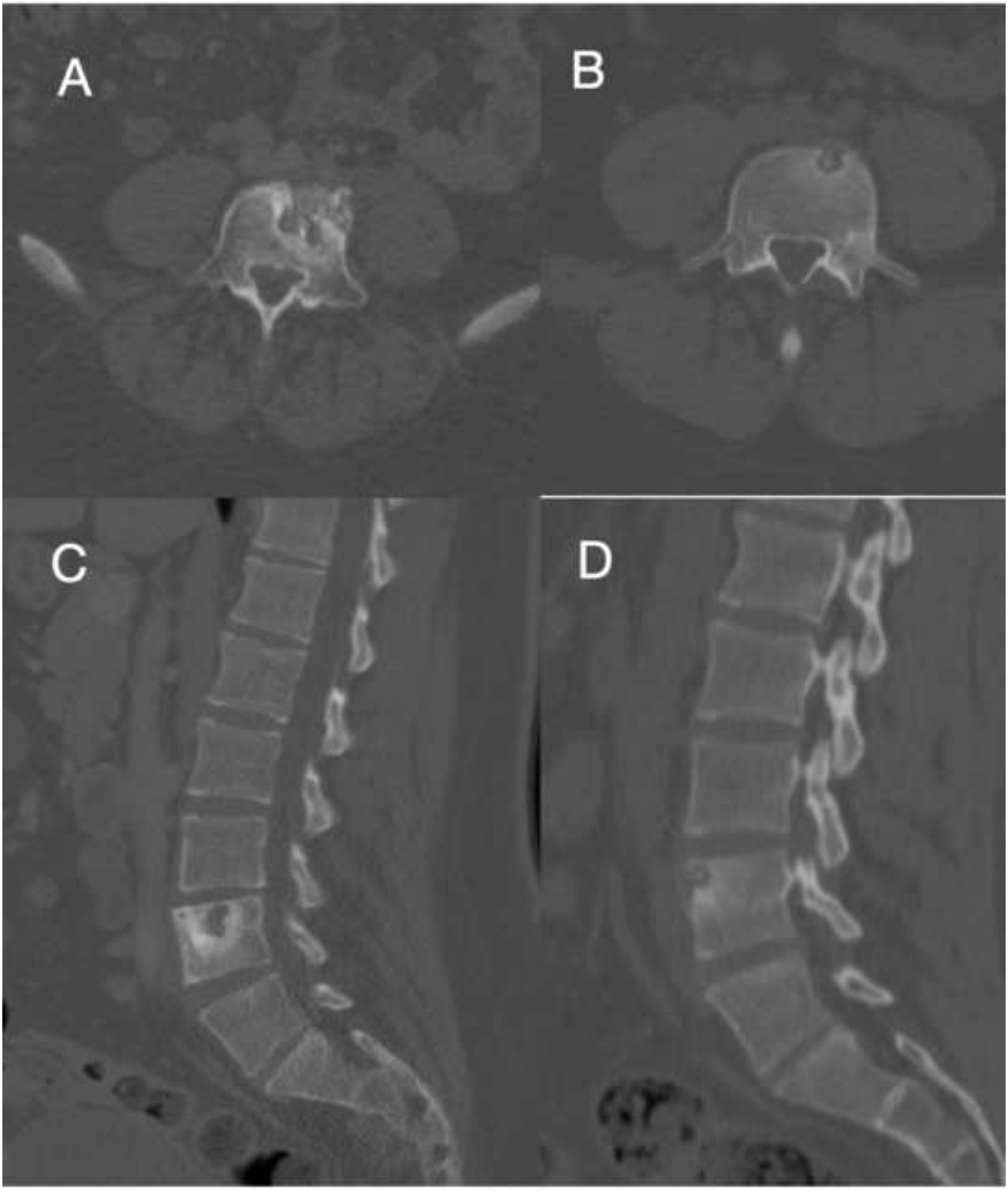

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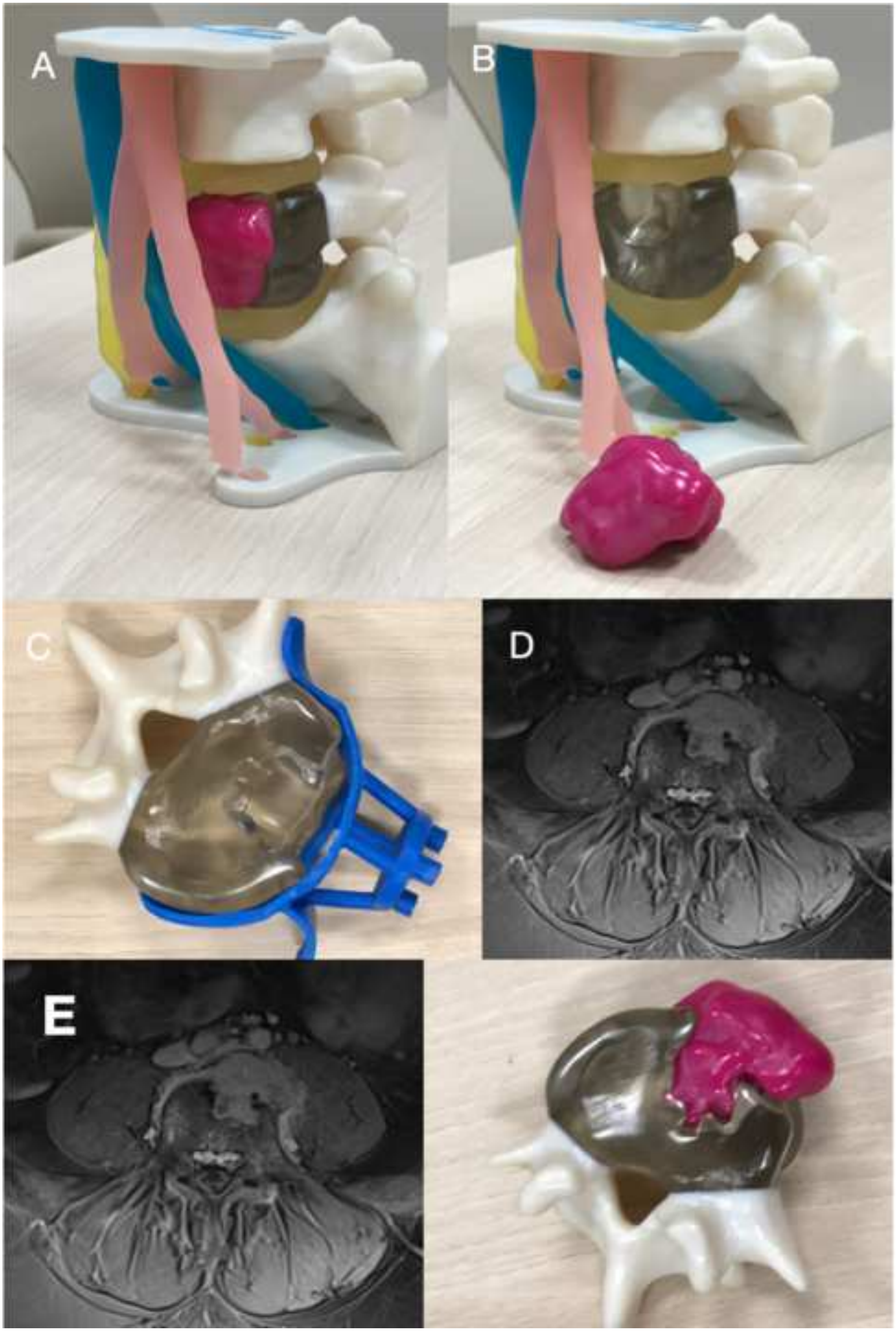

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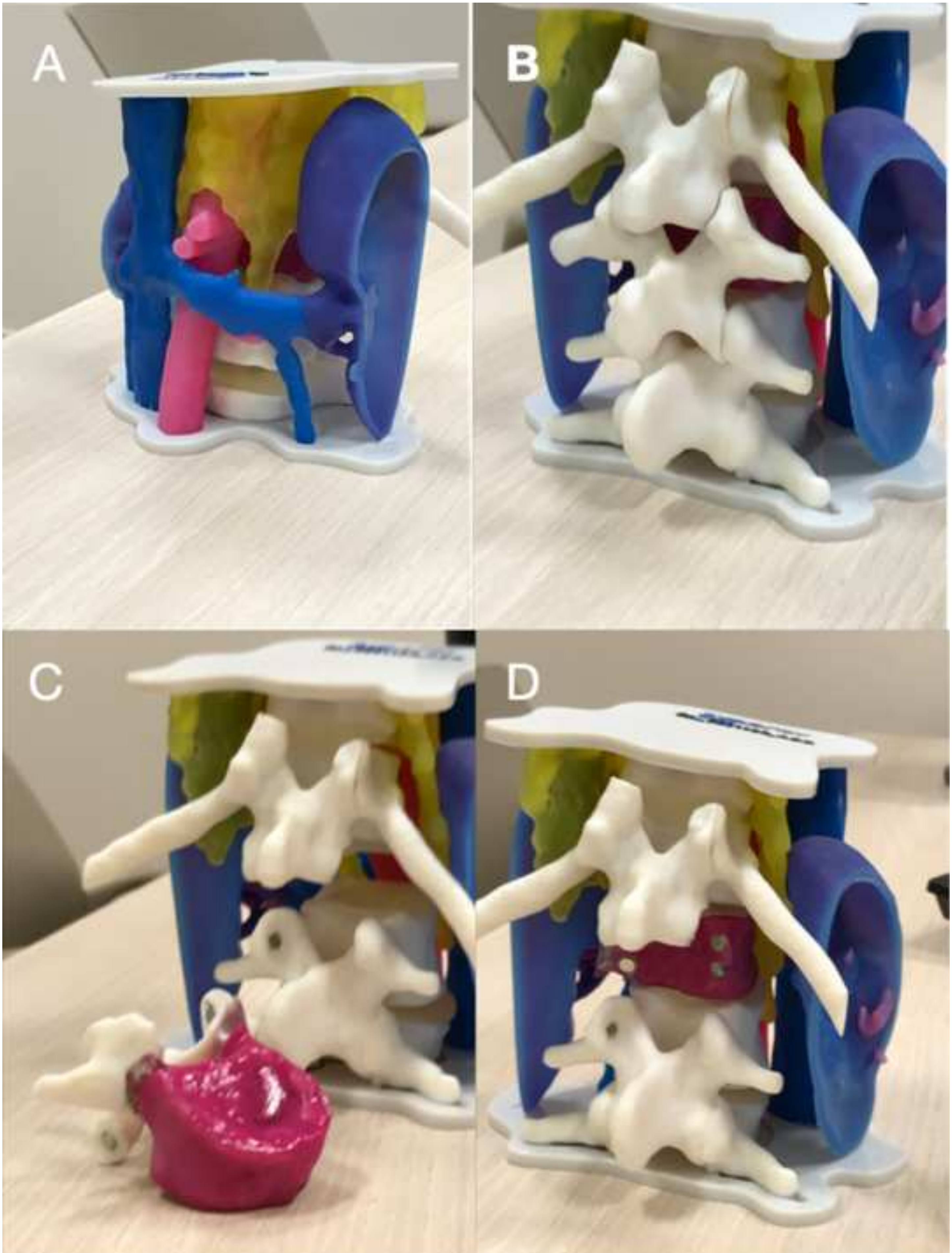

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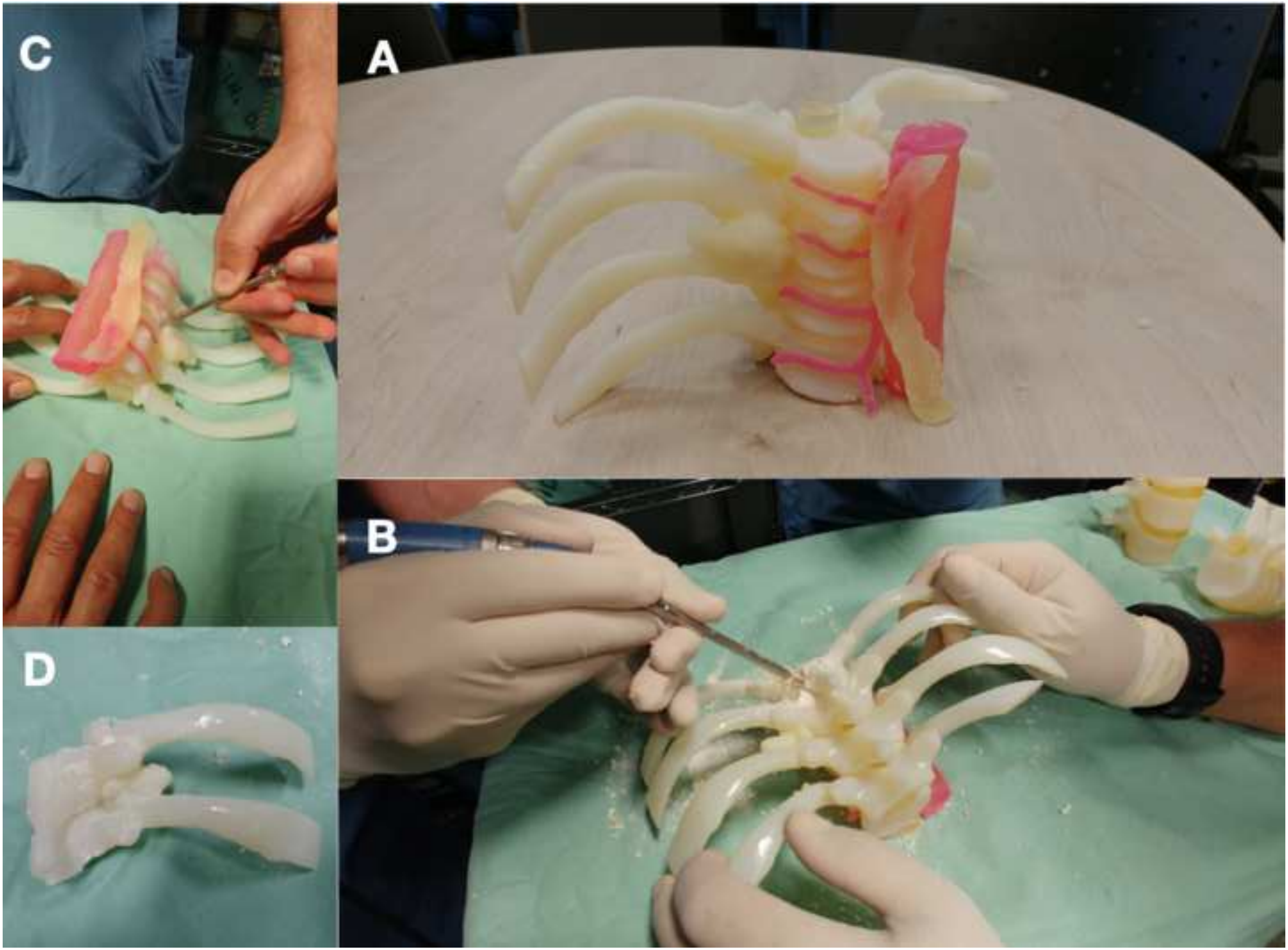

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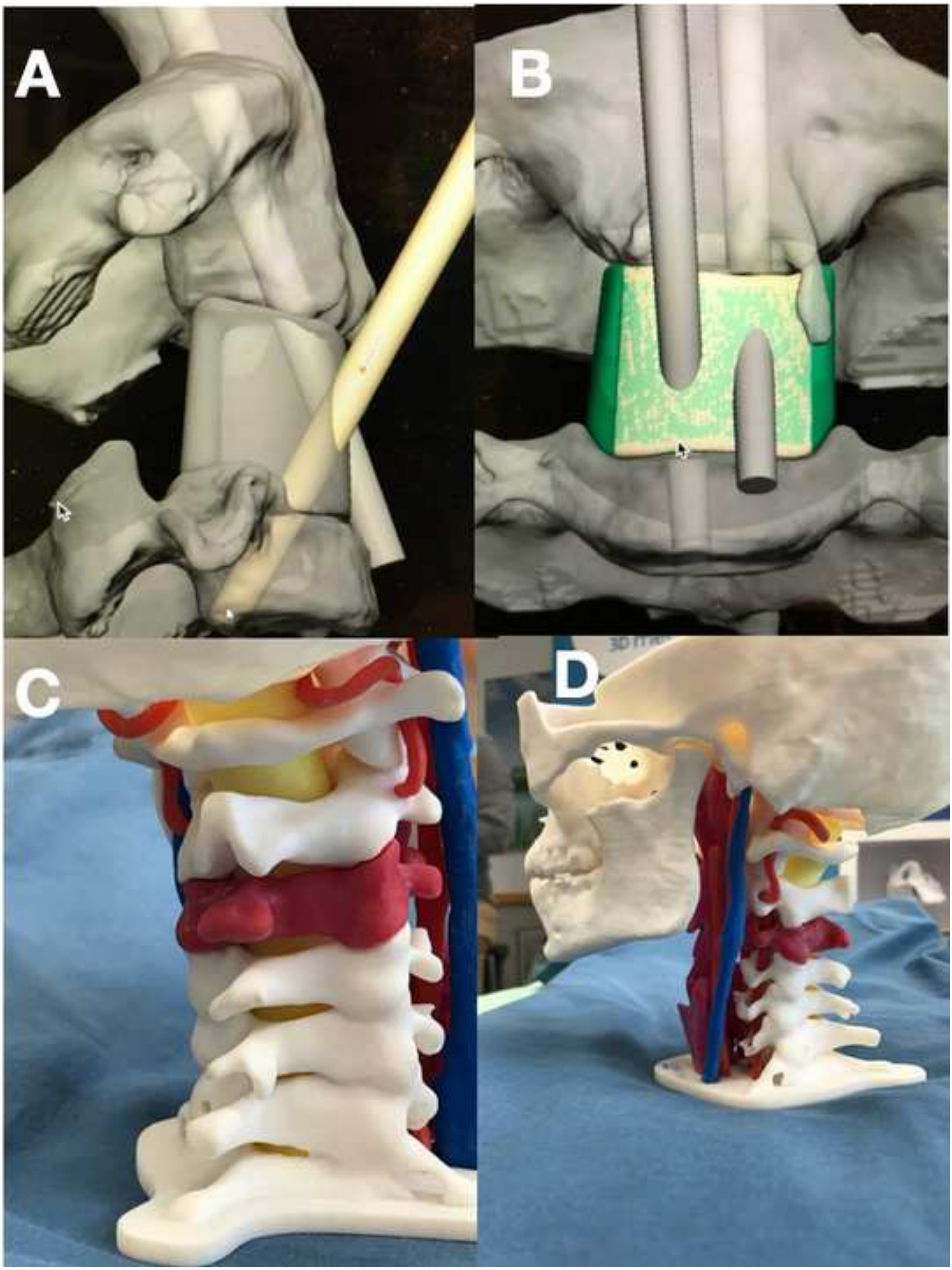

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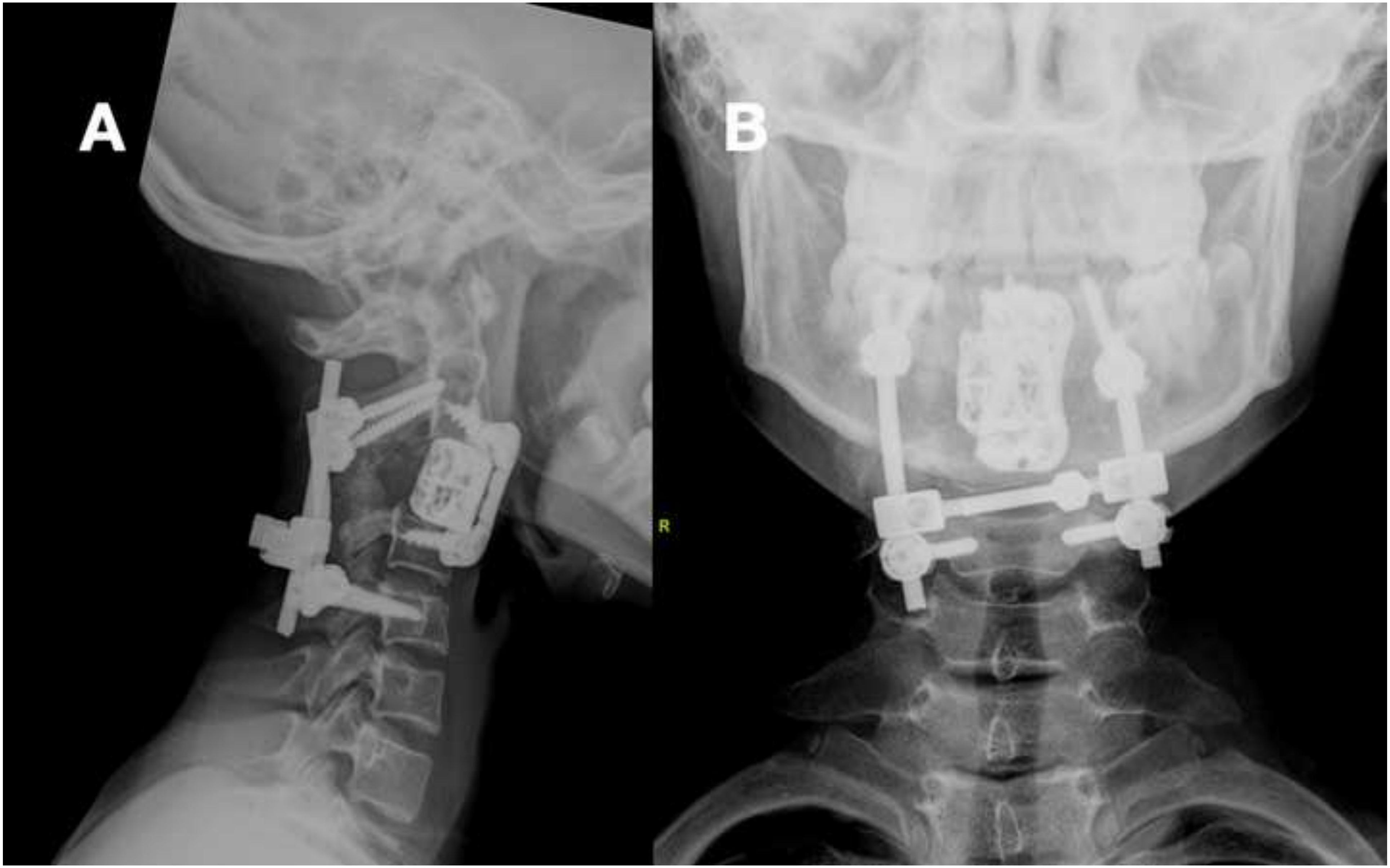

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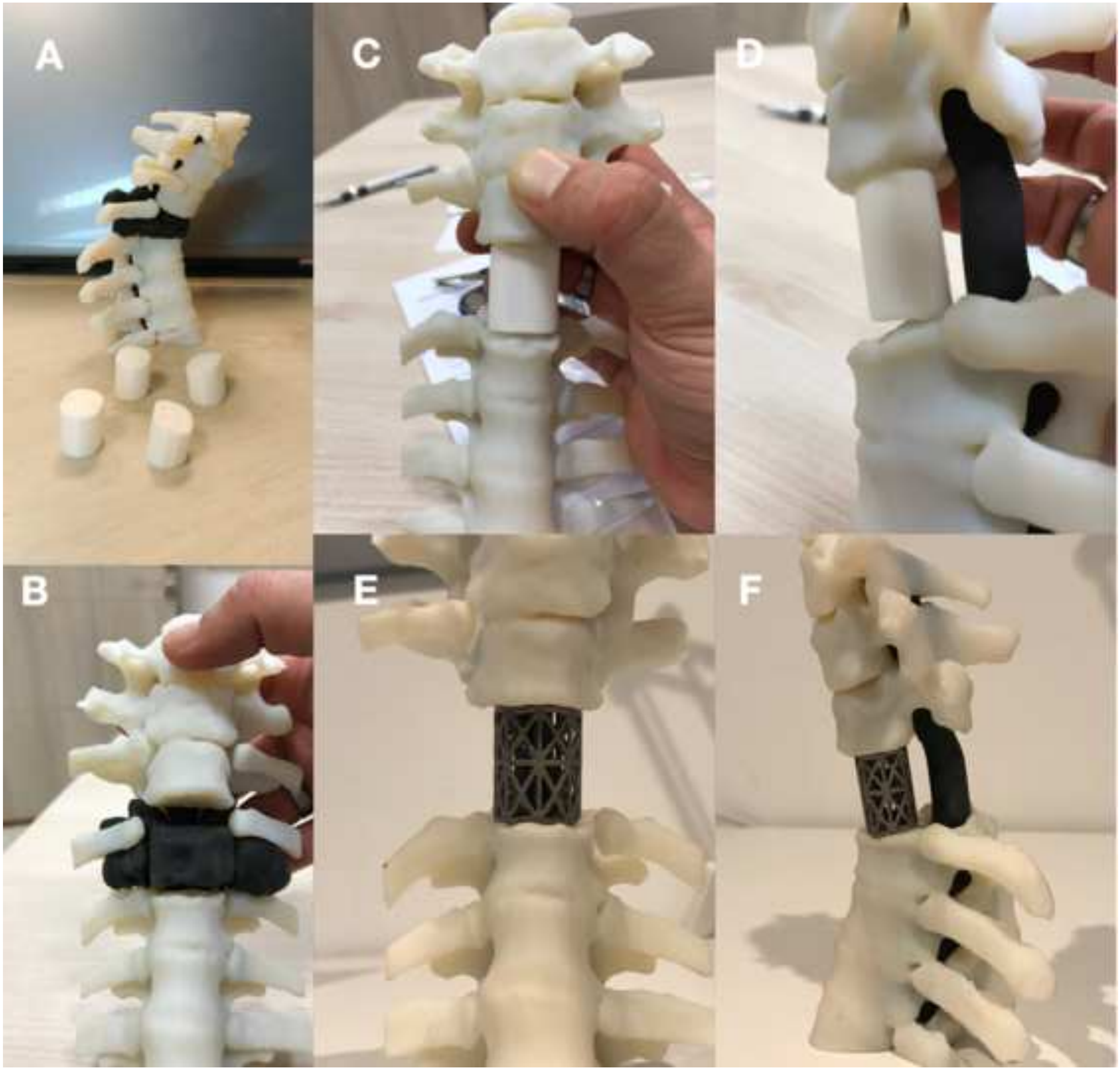
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