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## A Spine Robotic-Assisted Navigation System for Pedicle Screw Placement

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<b>Corresponding Author:</b>	Tzehong Wong, PhD, MD National Taiwan University Hospital Hsin-Chu Branch Hsin Chu city, Hsin Chu TAIWAN
<b>Corresponding Author's Institution:</b>	National Taiwan University Hospital Hsin-Chu Branch
<b>Corresponding Author E-Mail:</b>	tzehongwong@gmail.com
<b>Order of Authors:</b>	Hsuan-Yu Chen Xiu-Yun Xiao Chih-Wei Chen Hao-Kai Chou Chen-Yu Sung Feng Huei Lin Po-Quang Chen Tzehong Wong, PhD, MD
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**TITLE:**

A Spine Robotic-Assisted Navigation System for Pedicle Screw Placement

**AUTHORS AND AFFILIATIONS:**

Hsuan-Yu Chen<sup>1,2,3</sup>, Xiu-Yun Xiao<sup>4</sup>, Chih-Wei Chen<sup>1,4</sup>, Hao-Kai Chou<sup>1,4</sup>, Chen-Yu Sung<sup>4</sup>, Feng Huei Lin<sup>1</sup>, Po-Quang Chen<sup>2</sup>, Tze-Hong Wong<sup>2</sup>

<sup>1</sup>Institute of Biomedical Engineering, National Taiwan University, Taipei City, Taiwan

<sup>2</sup>Department of Orthopedic Surgery, National Taiwan University Hospital, Hsin-Chu Branch, Hsinchu City, Taiwan

<sup>3</sup>Department of Orthopedic Surgery, National Taiwan University Hospital, Hsin-Chu Biomedical Park Branch, Zhu-Bei City, Taiwan

<sup>4</sup>Point Robotics MedTech Inc., Hsinchu City, Taiwan

## Email addresses of co-authors:

Hsuan-Yu Chen (hychen83@gmail.com)

Xiu-Yun Xiao (s0900172@gmail.com)

Chih-Wei Chen (r00548016@gmail.com)

Hao-Kai Chou (adam1328x@gmail.com)

Chen-Yu Sung (jacksong1210@gmail.com)

Feng-Huei Lin (double@ntu.edu.tw)

Po-Quang Chen (chen.poquang@gmail.com)

## Corresponding author:

Tze-Hong Wong

(tzehongwong@gmail.com)

**KEYWORDS:**

Accuracy, surgical robotics, spine navigation system, pedicle screws, spine, computer-assisted navigation

**SUMMARY:**

This article presents a standardized surgical technique for robotic-assisted pedicle screw placement by using robotic-assisted navigational systems. We present a step-by-step protocol and describe the workflow and precautions of this procedure.

**ABSTRACT:**

Pedicle screw implantation has excellent treatment effects and is often used by surgeons in spinal fusion surgery. However, due to the complexity of human body anatomy, this surgical procedure is difficult and challenging, especially in minimally invasive surgery or patients with congenital anomalies and kyphoscoliosis deformity. In addition to the abovementioned factors, the surgical experience and technique of the surgeon also affect the recovery rates and complications of the patients after the surgical operation. Therefore, accurately performing pedicle screw implantation has is a constant topic of common concern for surgeons and

45 patients. In recent years, with the technological development, robot-assisted navigation  
46 systems have gradually become adopted. These robot-assisted navigation systems provide  
47 surgeons with complete preoperative planning before surgery. The system provides 3D  
48 reconstructed images of each vertebra, allowing surgeons to understand the patient's  
49 physiological characteristics more quickly. It also provides 2D images of sagittal, coronal, axial  
50 and oblique planes so that surgeons can accurately perform pedicle screw placement plan.

51  
52 Previous studies have demonstrated the effectiveness of robot-assisted navigation systems for  
53 pedicle screw implantation procedures, including accuracy and safety assessments. This step-  
54 by-step protocol aims to outline a standardized surgical technique note for robotic-assisted  
55 pedicle screw placement.

### 56 57 **INTRODUCTION:**

58 In the field of spinal surgery, spinal fusion surgery is a fundamental surgical procedure,  
59 especially posterior pedicle screw fixation, which can provide three-column support of the  
60 vertebrae and enhance the strength of biomechanics; thus, it has become one of the most  
61 commonly used surgical procedures<sup>1</sup>. In many early studies, the clinical effect of posterior  
62 pedicle screw implantation has been confirmed, and it has been widely used in surgery for  
63 many different spinal disorders, such as degenerative, traumatic, and complicated spinal  
64 conditions<sup>2</sup>.

65  
66 However, although the posterior lumbar spinal fusion surgery can achieve excellent treatment  
67 effects, it is still risky due to the human body anatomy. There are many vital tissue structures  
68 close to the pedicle, such as the central nervous system, nerve roots, and main blood vessels.  
69 The damage of these tissues during the surgical procedure may cause serious complications,  
70 such as vascular injuries, neurological deficits, or screw loosening<sup>2,3</sup>. Moreover, the surgeons  
71 and staff are exposed to additional radiation, particularly in the case of minimally invasive  
72 spinal procedures<sup>4</sup>. Surgeons may experience fatigue and hand tremors after lengthy and  
73 tedious spinal surgery procedures, such as screw placements, bone osteotomy, and nerve  
74 decompression<sup>5</sup>.

75  
76 The unsatisfactory rate of the pedicle screw placement procedure necessitated the proposal for  
77 a robotic-assisted navigation system to be applied in spinal surgeries to improve the surgery  
78 accuracy and patients' safety. Several studies on robotic-assisted navigation systems have  
79 demonstrated improvements in the safety, accuracy, and precision of pedicle screw placement,  
80 as well as decreased radiation exposure and operative times<sup>6-10</sup>. However, thorough screw  
81 trajectory planning, pre-operative planning with images, comprehensive robotic system with  
82 fixation device, and robot control software still need to be addressed to achieve this goal. This  
83 study focuses on the description of the robotic structure and the workflow of a self-developed  
84 navigation system (i.e., the Point spine navigation system (PSNS)) for robotic-assisted pedicle  
85 screw placement surgeries.

### 86 87 **System description and surgical protocol**

88 The PSNS comprises a navigation workstation that includes the following. (1) There is a user  
89 interface software responsible for image reading through three-dimensional (3D)  
90 reconstruction, pre-operative planning, spatial kinematic relationship calculation, and  
91 registration. (2) The PSNS uses infrared optical guidance systems to track the spatial position of  
92 surgical robots and patients. The infrared optical guidance system contains the following  
93 components: (i) an optical tracker that actively emits infrared light and performs stereo  
94 positioning through a dual camera (**Figure 1**); (ii) a marker sphere whose surface has a reflective  
95 coating with reflective properties for precise tool tracking; and (iii) a tool with a dynamic  
96 reference frame (DRF) that comprises a base and four marker spheres. To avoid the  
97 identification failure of the tracking system, each device has a unique DRF design and cannot be  
98 shared with each other. The DRF used includes a base frame (BF) attached to the base of the  
99 handpiece to confirm the handpiece position, an end-effector frame (EF) attached to the end of  
100 the handpiece to confirm the handpiece position, a fiducial frame (FF) anchored on the  
101 patient's bone to confirm the patient's position, and a probe whose tip is used to confirm the  
102 target position in 3D space. (3) There is a handpiece comprising a six degrees of freedom (DOF)  
103 Stewart platform, with one end of the robot equipped with an operation tool used for drilling  
104 the screw path. The handpiece is a robotic-assisted navigation system that assists surgeons  
105 toward the accurate placement of implants, such as pedicle screws, or positioning of surgical  
106 tools during spinal surgery. The movement of the surgical target is tracked as the robot  
107 automatically compensates for the correct target. The robot is designed as a semi-active system  
108 that offers surgical tool guidance; however, the actual surgery is performed by surgeons. The  
109 operating principle and equipment are illustrated in **Figure 2**.

110  
111 PSNS is indicated for procedures including but not limited to the following sample procedures:  
112 (i) open, minimally invasive, or percutaneous spinal surgery; (ii) spinal surgery site for thoracic,  
113 lumbar, or sacral vertebrae; (iii) posterior spinal fusion for trauma, degenerative stenosis  
114 disease, instability, spondylolisthesis, herniated disc, tumor, infection, or spinal deformity  
115 correction; (iv) placement of temporary or permanent devices, such as k-wires or needles, while  
116 performing vertebroplasty, or either transforaminal or interlaminar percutaneous endoscopic  
117 lumbar discectomy; and (iv) bone tumor excision, including the ablation of osteoid osteoma or  
118 tumor biopsy, in which the robot directed needles or guidewires to a given vertebral location.  
119 This procedure is contraindicated for those with an inability to tolerate anesthesia, surgical  
120 procedure, or when satisfactory navigation images have not been acquired.

121  
122 Note that the operation staff, including neurosurgeons and orthopedic surgeons, must be  
123 licensed and trained in guiding courses. All procedures for operating the robot during surgery  
124 need to follow the recommended standardized procedures to avoid causing harm to the patient  
125 or surgeon. Surgeons must possess conventional surgical experience to ensure that it is possible  
126 to switch back to conventional surgical instruments and complete the surgery when it is  
127 determined that the navigation is inaccurate, based on the surgeons' anatomical knowledge.

128  
129 **PROTOCOL:**

130

131 All procedures followed were in accordance with the ethical standards of the National Taiwan  
132 University Hospital (NTUH) Research Ethics Committee (REC) and the Helsinki Declaration of  
133 1975 (in its most recently amended version). Informed consent must be obtained from all  
134 patients if further clinical trial is prepared.  
135

136 NOTE: The anesthesia procedure can be categorized into three steps: pre-operative evaluation  
137 of the patient, intraoperative management, and postoperative management. During pre-  
138 operative evaluation, all patient data, including the thorough history and physical examination,  
139 should be collected and the staff should recognize patient comorbidities and how they relate to  
140 the anesthetic care of the patient. A thorough airway exam should be performed, and the staff  
141 should be aware of the anesthetic options to formulate a basic anesthetic care plan. During  
142 intraoperative management, the anesthesiologist should check the basic functions of the  
143 anesthesia machine, and apply basic physiologic monitors recommended by the American  
144 Society of Anesthesiologists, which include a pulse oximeter, electrocardiography, a  
145 noninvasive blood pressure device, and a temperature monitor, airway management options,  
146 pharmacology of inductions agents, and indications during an anesthetic induction.  
147 Intraoperative events, such as hypotension, hypertension, hypoxia, and oliguria, must be  
148 recognized, evaluated, and managed. Additionally, the staff must recognize when the patient  
149 meets the extubation criteria.  
150

### 151 **1. Pre-operative setting and planning**

152

153 NOTE: During surgery, sterile surgical drapes should be used to prevent contact with  
154 unprepared surfaces and to maintain surgical site sterility of the environmental surfaces,  
155 equipment, and patient's surroundings. To reduce the risk of pathogen transmission to both the  
156 patients and the surgical team, sterile surgical gowns should be worn over the scrub suits by  
157 the operating team during surgery.  
158

159 1.1. Remove all components that can affect fluoroscopy from the surgical site; this depends on  
160 the surgical plan according to each individual patient.  
161

162 1.2. Place the patient in a prone position after administering anesthesia and prepare as per  
163 surgical requirements.  
164

165 NOTE: All anesthesia procedures must be performed under the supervision of an  
166 anesthesiologist and each plan should be adjusted according to each individual patient.  
167

168 1.3. Clean and sterilize the surgical site of the patient.  
169

170 1.4. Cover the OP-site at the surgical site of the patient.  
171

172 1.5. Place the sterile surgical drape on the patient, except at the surgical site.  
173

174 1.6. Anchor the FF to the patient; users can choose one of the following two methods according  
175 to their needs.

176  
177 1.6.1. Anchoring to the iliac bone (applicable surgical site: L5 or S1).

178  
179 1.6.1.1. Place two percutaneous wires ( $\Phi = 1.5$  mm) on the posterior iliac crest and check the  
180 entry point under fluoroscopy. Repeat the step if surgeon has a concern about the entry point.  
181 Mark the entry point by using a marker pen.

182  
183 1.6.1.2. Insert the first percutaneous pin ( $\Phi = 5$  mm, L = 140 mm) into the patient's posterior  
184 iliac crest by using a power drill (1000 RPM).

185  
186 1.6.1.3. Place the FF along with the first percutaneous pin. Adjust the FF until it is recognized by  
187 the optical tracking camera. Fix the FF to the first percutaneous pin using a screwdriver.

188  
189 1.6.1.4. Insert the second percutaneous pin ( $\Phi = 5$  mm, L = 140 mm) along with a hole on the FF  
190 using a power drill (1000 RPM). Fix the screw on the FF to the second percutaneous pin using  
191 screwdriver.

192  
193 NOTE: According to the manual of the optical tracking system, the marker sphere can be  
194 identified within 3 m from the optical tracker.

195  
196 1.6.2. Anchoring to the current or adjacent vertebral spinous process with a clamp applicable  
197 surgical site: thoracic, lumbar, or sacral vertebrae.

198  
199 1.6.2.1. Place a wire ( $\Phi = 1.5$  mm) on the patient's back as a reference under fluoroscopy.  
200 Check the surgical field under fluoroscopy. Repeat the step if surgeon has a concern about the  
201 surgical field. Mark the surgical field by using a marker pen.

202  
203 1.6.2.2. Incise the skin tissue on surgical field using a surgical scalpel. Fix the FF to the spinous  
204 process using a screwdriver. Due to the difference of bone mineral density, have the surgeon  
205 determine if the FF is anchored on spinous process firmly.

206  
207 1.7. Check whether the equipment and components of PSNS have been prepared, including the  
208 handpiece, the optical tracking system, the robotic workstation, and the navigation toolkit (i.e.,  
209 probe) (**Figure 3 & Figure 4**).

210  
211 NOTE: Avoid interfering with the surgical staff; Avoid blocking the optical tracking camera;  
212 Ensure the tracker is stable and recognized by the optical tracking system; Sterilize the  
213 navigational toolkit and place it on the operating table.

214  
215 **2. Spatial labeling and registration**

216

217 2.1. Transfer the patient's preoperative CT images to the system through DVD or USB and crop  
218 the image size to adjust the orientation based on surgical needs. The system provides virtual  
219 surgical guided images, including sagittal, coronal, axial, and oblique planes, and customized 3D  
220 reconstructions for each vertebra.

221  
222 2.2. As the PSNS software provides the labeling interface, ask the surgeon to label each  
223 vertebra with the anterior-posterior view and lateral view, differentiating the intervertebral  
224 disc for the subsequent steps to be identified.

225  
226 2.3. Select the optimal screw length and implant dimensions based on the device software.

227  
228 2.4. Plan the optimal positioning and trajectory of the screw based on the 3D and multi-planar  
229 image reconstruction of the preoperative CT scan.

230  
231 2.5. Confirm whether all the planned screws are correct and appropriate.

232  
233 2.6. Enter the DRF monitoring interface in the PSNS software that presents multiple planar  
234 views (include 3D volume and three cross-sectional planes on the side). All the DRFs should be  
235 inside the vision area of the optical tracking system (according to the user instructions, the  
236 recommended best recognition range is range B.) When the DRF vector arrow indicating the  
237 tracker is displayed on the user interface, it is stably recognized by the tracking system (**Figure**  
238 **5**).

239  
240 2.7. Perform a subperiosteal dissection bilaterally along the spinous process, the laminae out to  
241 the tips of the transverse processes of all the levels. Remove the facet joint capsules to expose  
242 the joints. The use of self-retained retractors aid in vertebra exposure by holding the  
243 musculature off to the side.

244  
245 2.8. Perform registration procedures, including landmark registration and surface matching.  
246 Follow the sequence below to ensure the correctness of the registration result.

247  
248 2.8.1. Landmark registration

249  
250 2.8.1.1. Select at least four non-coplanar feature points (such as the spinous process, the  
251 laminar, and the transverse process) on the patient's pre-operative 3D reconstruction CT  
252 images.

253  
254 2.8.1.2. Use the tip of probe to keep in contact with the first feature point selected in step  
255 2.8.1.1 in the actual surgical area.

256  
257 2.8.1.3. Press the **probe selection** button on the software interface to confirm the access point.

258  
259 2.8.1.4. Repeat steps 2.8.1.2-2.8.1.3 until the four feature points selected in step 2.8.1.1 are  
260 confirmed.

261  
262 2.8.1.5. Press the **calculation** button on the software interface; the system will calculate the  
263 result of the landmark registration and present it in the software interface.  
264  
265 2.8.1.6. The acceptance criteria for the registration accuracy must meet the needs of the  
266 clinical indications (<5 mm). If the result is not satisfactory, repeat steps 2.8.1.1-2.8.1.5 until the  
267 registration result meets the acceptance criteria.

268  
269 NOTE: Ensure that the validity of using the probe to obtain the position information of the bone  
270 surface, such as clearing the soft tissue on the bone surface and avoiding the dangling of the  
271 probe tip when collecting points.

## 272 273 2.8.2. Surface matching

274  
275 2.8.2.1. Use the probe tip to continuously contact any point on the bone surface in the actual  
276 surgical area.

277  
278 2.8.2.2. Press the **probe selection** button on the software interface to confirm the access point

279  
280 2.8.2.3. Move the probe (make probe different from previous pick point), and repeat steps  
281 2.8.2.1-2.8.2.2 until at least 50 pick points are completed.

282  
283 2.8.2.4. Press the **calculation** button on the software interface; the system will calculate the  
284 surface matching result and present it on the software interface.

285  
286 2.8.2.5. The acceptance criteria for the registration accuracy must meet the needs of the  
287 clinical indications (<0.5 mm). If the result is not satisfactory, repeat steps 2.8.2.1-2.8.2.4 until  
288 the registration results meet the acceptance criteria.

289  
290 2.9. Use the probe to select obvious anatomical landmarks (such as spinous process, transverse  
291 processes, facet joint) of the actual surgical area for confirmation once the registration result is  
292 accepted (**Figure 6**).

293  
294 NOTE: Appropriate reflection and reception of the infrared light must be maintained during  
295 surgery. If the optical tracking system cannot recognize the markers, the software interface will  
296 display a red light reminder. The camera should be adjusted such that the surgical field is at the  
297 center of the camera's detection range, and the tracker should be protected from light and  
298 blood.

## 299 300 3. Robot assembly and motion

301  
302 3.1. Cover the handpiece with sterilization drapes and install the surgical instruments on the  
303 robot (e.g., trocar ( $\Phi = 5$  mm) and k-pin ( $\Phi = 1.8$  mm)).

304



305 3.2. Adjust the angle and position of the handpiece in space according to the following  
306 instructions (steps 3.2.1-3.2.2) so that the handpiece is within the compensation range (within a  
307 distance of one centimeter and an included angle of 4 degrees from the planned path).

308  
309 3.2.1. Angle adjustment: Turn the angle of the handpiece in space so that the two circles  
310 representing the angle of the handpiece coincide on the software interface.

311  
312 3.2.2. Position adjustment: horizontally and vertically move the position of the handpiece in  
313 space, so that the dots representing the position of the handpiece on the software interface are  
314 aligned with the entry points of the planned path.

315  
316 NOTE: When steps 3.2.1 & 3.2.2 are completed at the same time, the handpiece will  
317 automatically activate the active compensation function to maintain the angle and position of  
318 the instrument to conform to the pre-planned path (**Figure 7**).

319  
320 3.3. Determine the robot's operating status by judging the marker color of the robot displayed  
321 on the UI. If it is green, it can be operated, if it is red, it cannot be operated.

322  
323 NOTE: If the handpiece comes in contact with the patient or the surrounding obstacles, an  
324 emergency stop button located above the navigation workstation housing can be pressed by  
325 the surgeon or technician. Regular maintenance of the robot should be performed. The  
326 platform must be recalibrated for the kinematics parameters after 250 uses. The trocar and k-  
327 pin must be discarded after a single use.

#### 328 329 **4. Pedicle preparation and screw insertion**

330  
331 4.1. Activate the drill function of the handpiece, and drill the instruments mounted on the front  
332 end (including K-pin:  $\Phi = 1.8$  mm and trocar:  $\Phi = 5$  mm) into the patient's body along the  
333 planned path.

334  
335 4.2. Use the c-arm to confirm the position of k-pin and trocar.

336  
337 4.3. If the k-pin and trocar positions are not correct under fluoroscopy, remove the k-pin and  
338 trocar. Then, using the handpiece, drill into the pedicle again until the k-pin and trocar insert  
339 into prone positions under fluoroscopy (refer to 4.3.1-4.3.2).

340  
341 4.3.1. Under AP view, determine whether the instrument is located in the oval area formed by  
342 the pedicle in the perspective image.

343  
344 4.3.2. Under LAT view, determine whether the instrument is within the range of the pedicle and  
345 vertebra.

346  
347 4.4. Replace K-pin and trocar with guidewires ( $\Phi = 1.5$  mm, L = 400 mm) once the positions are  
348 appropriate.

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**4.5. Insert the pedicle screw through the guidewires.**

4.6. Repeat steps 4.1–4.4 to complete all surgical planning paths.

NOTE: As for postoperative management, patients should be monitored in the post-anesthesia recovery unit (PACU) and the post-operative analgesia options should be selected. The basic PACU events, such as nausea, pain, hypotension, hypertension, and hypoxia, should be evaluated. Additionally, the staff should recognize when the patient meets the criteria for PACU discharge.

**REPRESENTATIVE RESULTS:**

The safety and accuracy of robotic-assisted pedicle screw placements have been addressed in several studies<sup>6,11</sup>. We match the vertebrae with pre-operative planning images under an optical tracking system in the proposed method. After determining the planned surgical path, this information was transferred to the handpiece through the handpiece control unit. The navigation system integrates the tracking information and displays it on the monitor during the surgery. Furthermore, the screen displays the admission path on the spine and the positions of the instruments.

In our previous study<sup>12</sup>, a low overall screw malposition rate of 1.7% from a total of 59 screws were placed on 30 porcine vertebrae through the PSNS was demonstrated (**Figure 8**). Surgical procedures proceeded smoothly while using the PSNS and these 59 pedicle screws were assessed by postoperative CT scans. 51 screws (86.4%) fell into group A, 7 screws (11.9%) fell into group B, and 1 screw (1.7%) fell into group E according to the Gertzbein–Robbins classification<sup>12</sup>. No spinal canal perforations or injuries to any other major vessels were found and all pedicle screws were inserted within the safe zone. We recorded the tip position data at a frequency of 60 Hz and a linear regression curve was calculated with the optical tracking system during the surgery. Differences including the angle, shortest distance, and entry point between the actual pedicle screw position and preoperative planning path were also recorded<sup>12</sup>.

**FIGURE AND TABLE LEGENDS:**

**Figure 1: Working principle of optical tracking system<sup>13</sup>.** The optical tracker will actively emit infrared light and perform stereo positioning through dual camera.

**Figure 2: Working principles of spine navigation system.** The application process of the system includes robot control, user interface, and optical sensing

**Figure 3: Spine navigation system, including handpiece, optical tracking system, robotic workstation, and navigation toolkit. (i.e., probe)**

**Figure 4: Schematic diagram of operation room configuration, users must refer to the schematic diagram to set up the PSNS in the operating room.**

393 **Figure 5: DRF monitoring interface in the software.** Users can confirm the current status of all  
394 DRFs according to the display on the interface.

395  
396 **Figure 6: Registration accuracy verification interface in the software.** Use probe to select a  
397 specific anatomical feature (such as spinous process, transverse processes, facet joint) in the  
398 actual surgical area, and the system will calculate the distance from the probe tip to the  
399 anatomical feature as a reference for accuracy.

400  
401 **Figure 7: Navigation interface in the software.** Using a 3D reconstructed bone model and  
402 virtualized pedicle screw to provide guidance for the surgical path.

403  
404 **Figure 8: Postoperative CT scans assessed according to Gertzbein and Robbins classification**  
405 **with an example of grade A (a), grade B (b) and grade E (c) <sup>14</sup>.**

406  
407 **DISCUSSION:**  
408 Since 1990, there have been rapid developments in surgical applications involving the use of  
409 robots. The available robotic technologies have been optimized, resulting in improved accuracy,  
410 overcoming the tremor in human hands, and reduced matching and registration times of  
411 navigation systems<sup>15</sup>. The benefits of surgical robot assistance include: (1) immediate  
412 standardization without lengthy learning processes; (2) surgeons can precisely follow the pre-  
413 operative plan, which is superimposed on a CT-based image through the user-interface; (3)  
414 reduction of radiation exposure to surgeons and operating staff; and (4) improved accuracy,  
415 especially while facing complex anatomy or complicated revision surgery.

416  
417 Despite the widely accepted use of pedicle screws, freehand pedicle placement techniques  
418 depend largely on anatomic landmarks, image guides, and the surgeons' experience. Even with  
419 experienced surgeons, the implant malposition rates are in the range of 5.1–31%, as described  
420 in multiple review studies<sup>3,16</sup>. Many surgeons accept deviations between 2 and 3 mm while  
421 assessing the accuracy of screw positions, as this deviation rate rarely becomes symptomatic.  
422 Lonstein et al. reported that 5.1% of 4,790 screws breached the cortical bone in their meta-  
423 analysis study, and approximately 0.2% of these caused neurological symptoms<sup>17</sup>. Additionally,  
424 even minor screw deviations may result in symptoms and surgeons may be hesitant to operate  
425 again. Therefore, a great variety of systems offering spinal image guidance such as  
426 electromagnetic navigation, intra-operative 3D fluoroscopy and CT navigation, percutaneous  
427 reference frames, and robotic-guided surgery are under research or in clinical use. These  
428 technologies allow surgeons to determine precise pre-operative and intra-operative execution  
429 plans, including pedicle screw length and diameter, even in the presence of severe deformities  
430 and lack of anatomic landmarks.

431  
432 The use of robotic-assisted pedicle screw placements is encouraging due to its accuracy of up to  
433 98.3%<sup>12</sup>. Despite the overall high accuracy of pedicle screw placement under PSNS, the robot  
434 system failed to adequately register 10–20% of the conditions during our testing. In conditions  
435 of such as high-degree of curvature, obesity, osteoporosis, loosening of previously placed  
436 hardware during revision surgery, poor-quality intra-operative fluoroscopic imaging, physical

437 limitations of the handpiece extensibility, device failure, mechanical movement, and technical  
438 issues, may result in difficulties with the registration and may require reverting to a freehand  
439 pedicle screw placement. Spine surgeons should possess traditional surgical experience to  
440 determine whether the navigation system is working appropriately and be able to switch to  
441 traditional surgery should the robotic system fail. Additionally, currently, PSNS is indicated for  
442 thoracolumbar pedicle screw implantation, and the accuracy of this system is 2 mm. In clinical  
443 surgery, the error tolerance of cervical pedicle screw implantation is approximately 0.2–0.5  
444 mm; thus, this system is not suitable for cervical surgery at present.

445  
446 PSNS comprising a handpiece can be used in combination with surgical tools to directly drill into  
447 the vertebra. The device footprint is small and occupies little space in the operating room.  
448 These features are different from other navigation robotic spinal surgery systems, making  
449 spinal navigation surgery more flexible and convenient for surgeons. The PSNS consists of  
450 image registration and matching, robotic and navigation technology, and precise equipment  
451 manufacturing. The system relies on these components working together appropriately as  
452 errors may occur if any one of these components fails. The spatial positioning of the anatomy at  
453 the surgical site will be relatively fixed after the images are acquired. Factors such as excessively  
454 soft tissue disturbance, decompression or osteotomy, long segment surgeries over 3 vertebrae,  
455 or the amount of respiratory tidal volume may cause navigational deviations. If the surgeon  
456 suspects a navigational deviation, the probe can be used to select the anatomical landmarks for  
457 confirmation (e.g., spinous process or facet joints). If the position is correct, the operation can  
458 continue. However, if the position is incorrect, some possible causes and solutions are as  
459 follows: (1) The dynamic reference frame-fiducial frame is moved during the operation. The  
460 surgeon should restrict the dynamic reference frame-fiducial frame and registration again. (2)  
461 There is relative displacement between the anatomical structures, such as after deformity  
462 correction, caused by the operation. The surgeon should re-scan the fluoroscopy to obtain new  
463 images for surgery. According to previously published research, robot-assisted navigation  
464 systems can reduce the time taken for each pedicle screw insertion; however, the operative  
465 time increases due to the robot setup and registration<sup>10</sup>.

466  
467 Several limitations of robot-assisted surgery still exist, such as registration problems including  
468 difficulty in landmark accessing, incompatibility in minimally invasive surgery and time  
469 consuming, patients being exposed to additional radiation, tool skiving due to lack of live-  
470 intraoperative feedback, impact on traditional spine training, dependence on technology, and  
471 high costs. PSNS has certain limitations: first, the surgeon needs to spend time to learn the  
472 PSNS system thoroughly; second, it is heavy for the surgeons to hold it. Our team will focus on  
473 making the user learning curve easier and provide a supporting arm for reducing the weight of  
474 the handpiece. Nevertheless, we believe that there are continuous developments in robotic-  
475 assisted navigation systems, which have potential for improving surgical outcomes.

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481 collection and analysis, decision to publish, or preparation of the manuscript.

482

#### 483 **DISCLOSURES:**

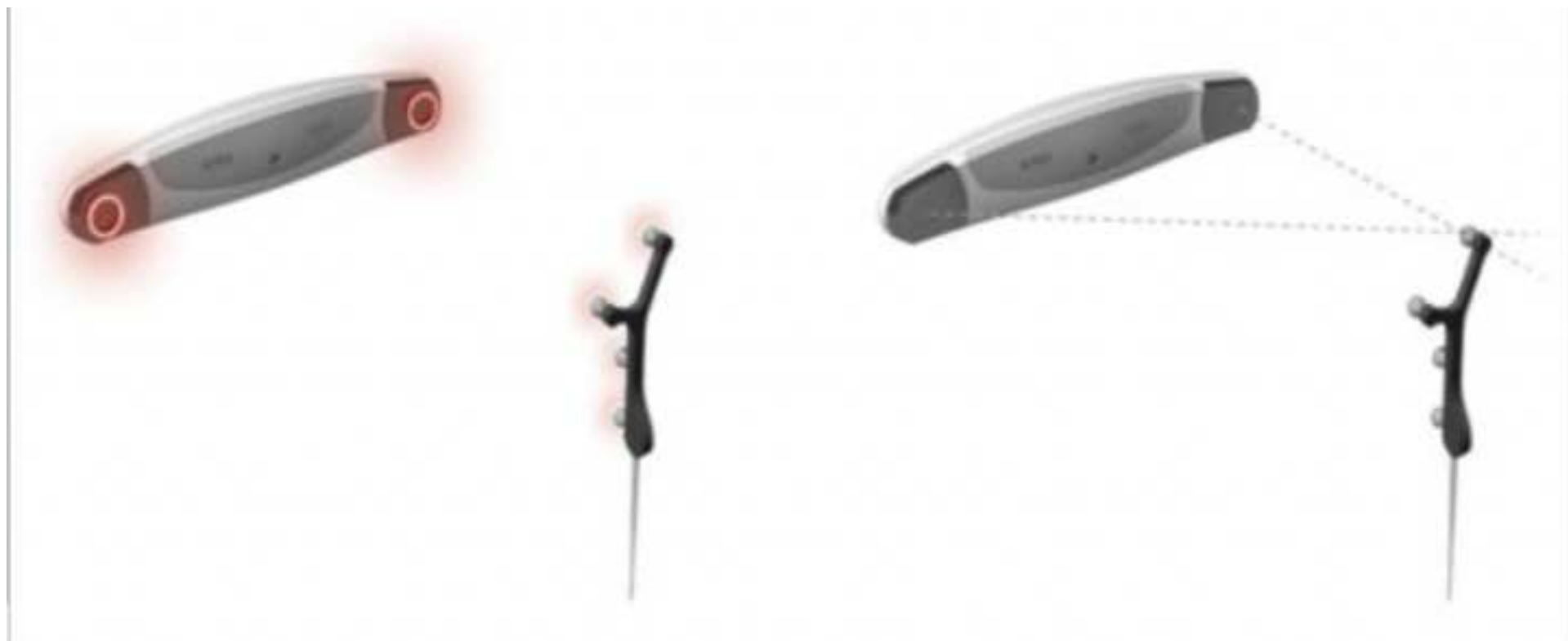
484 Point Robotics MedTech Inc employed authors Xiu-Yun Xiao, Chih-Wei Chen, Hao-Kai Chou, and  
485 Chen-Yu Sung. This study was partially supported by Point Robotics MedTech Inc., which  
486 provided the robot system. The authors declare that the point spine navigation system (PSNS)  
487 assessed in this study is a product in development.

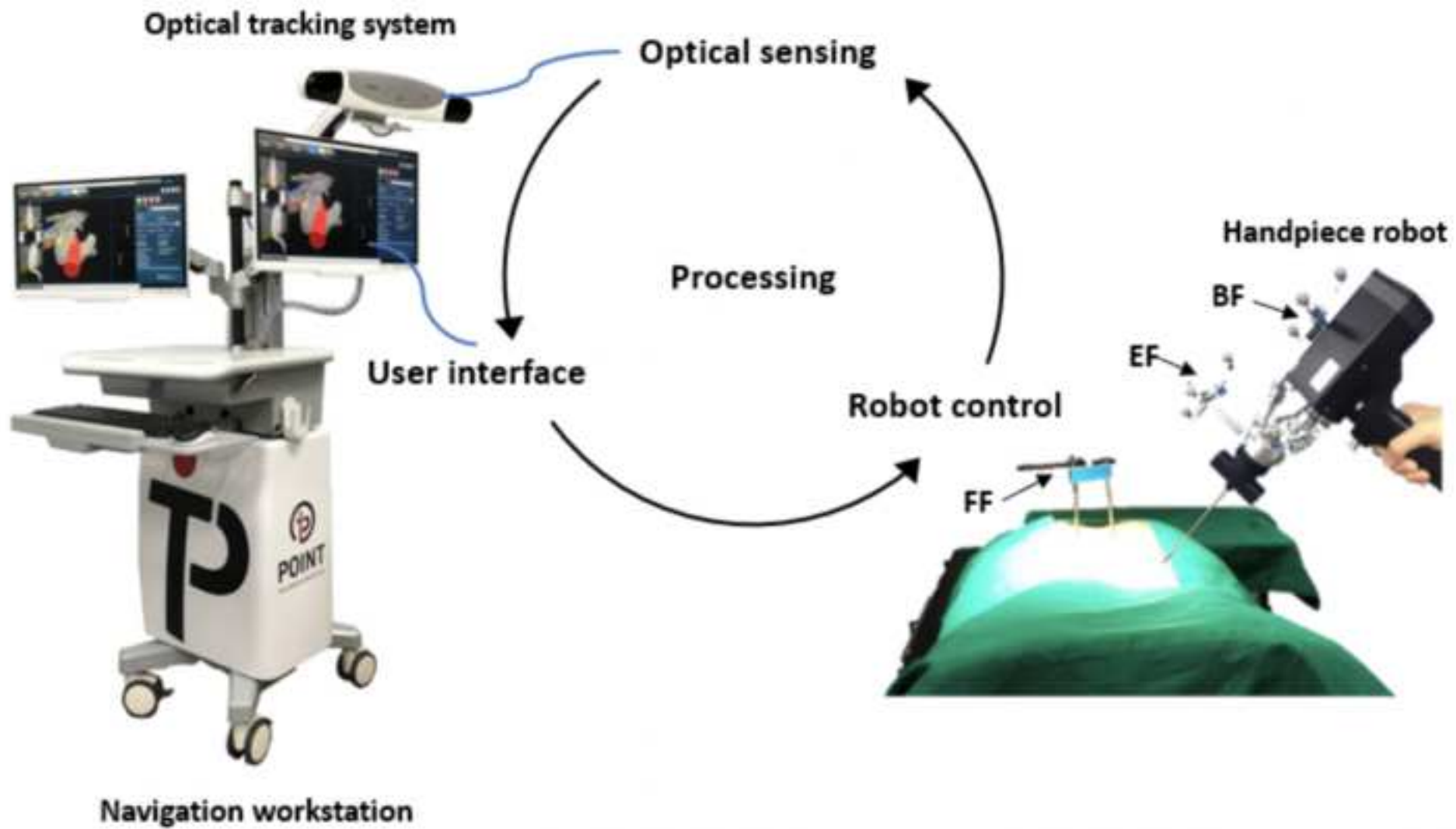
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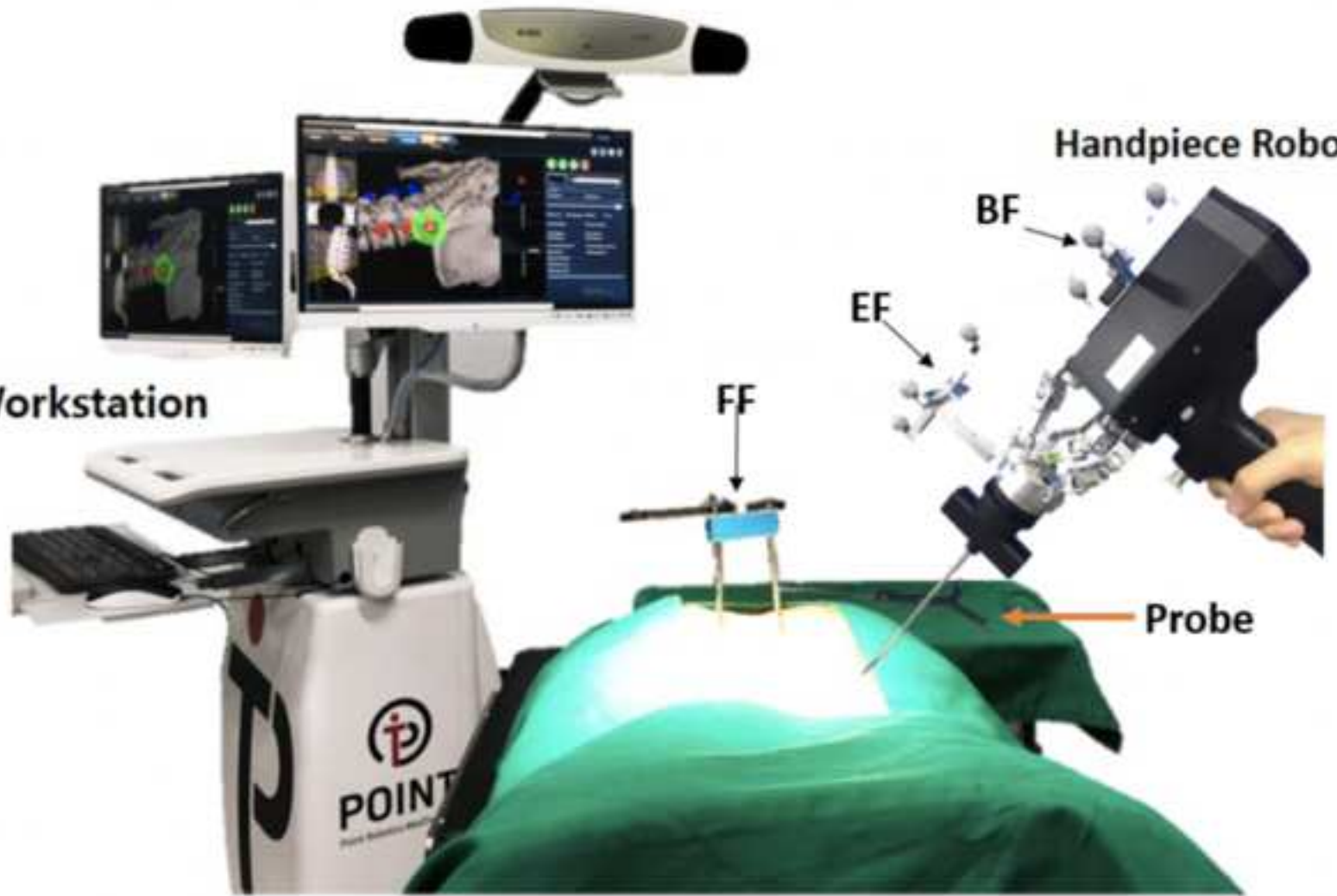




optical tracking system

Handpiece Robot

Navigation Workstation



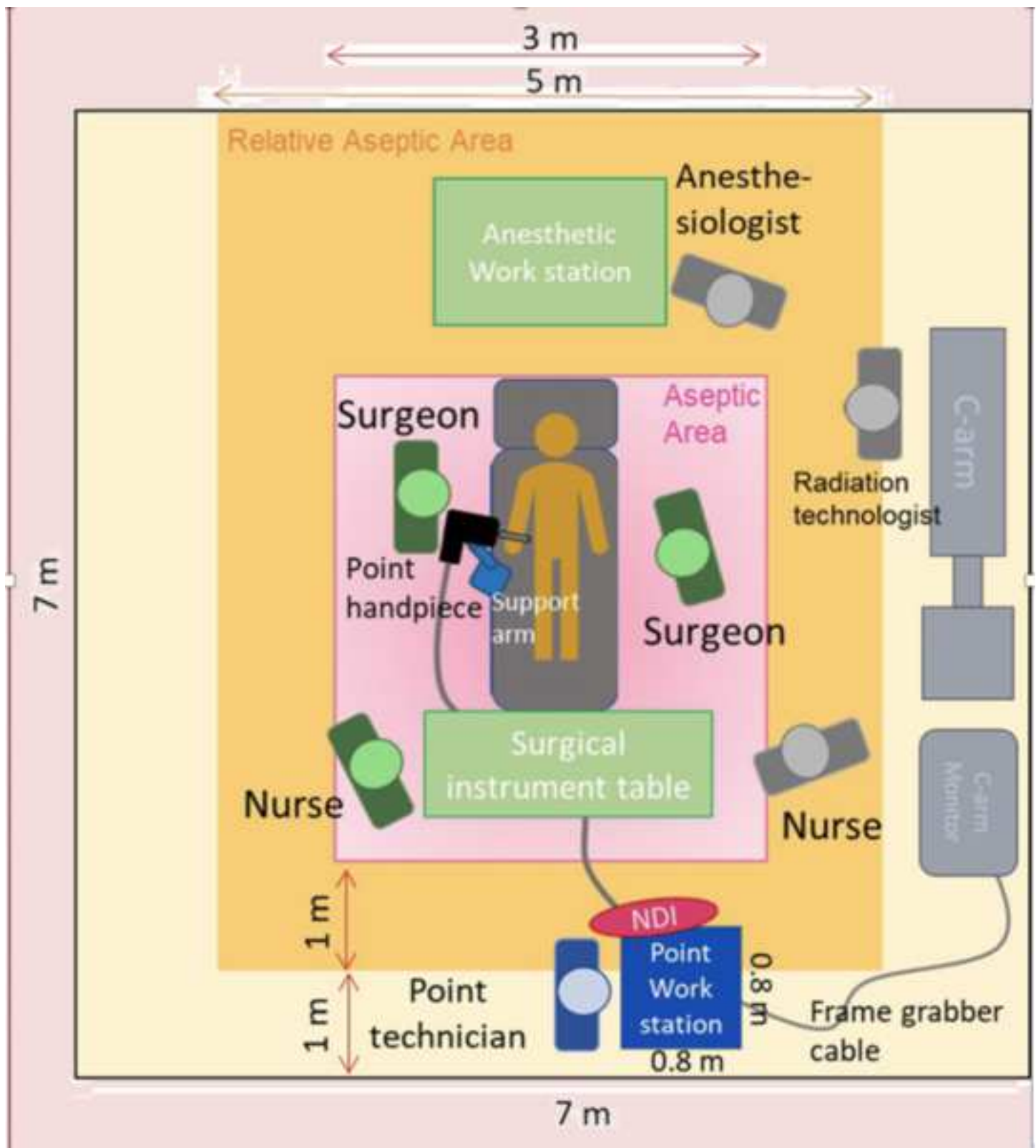
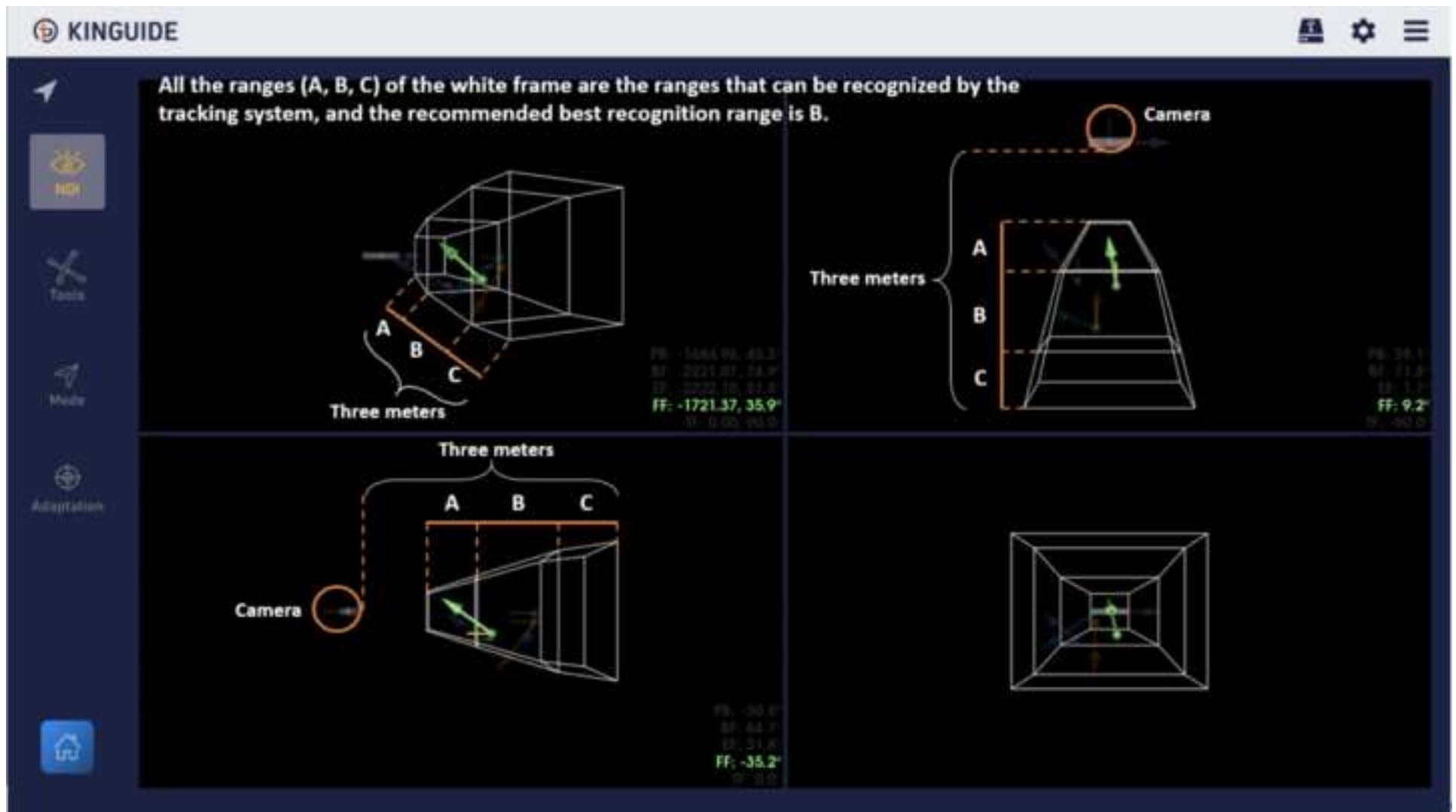
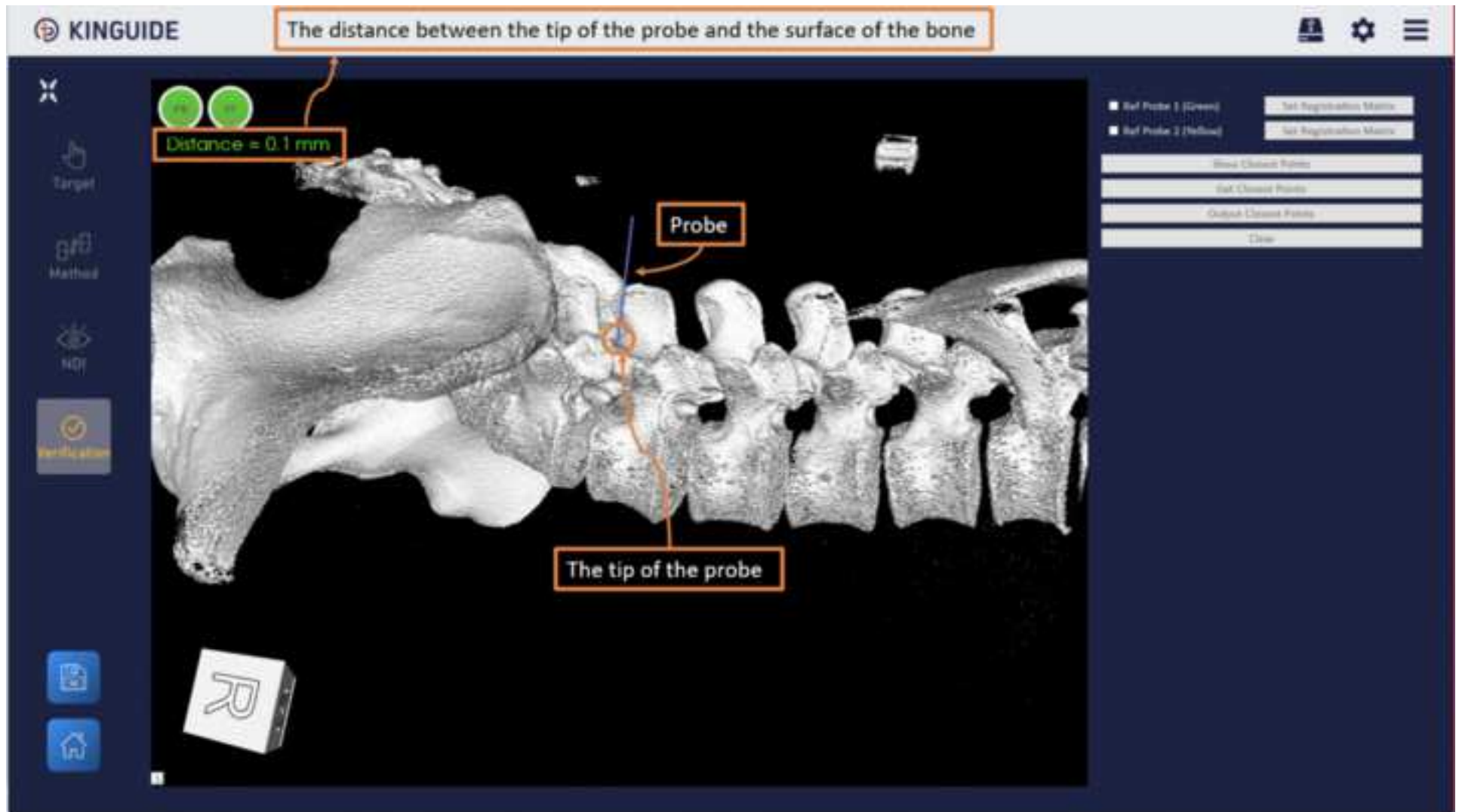
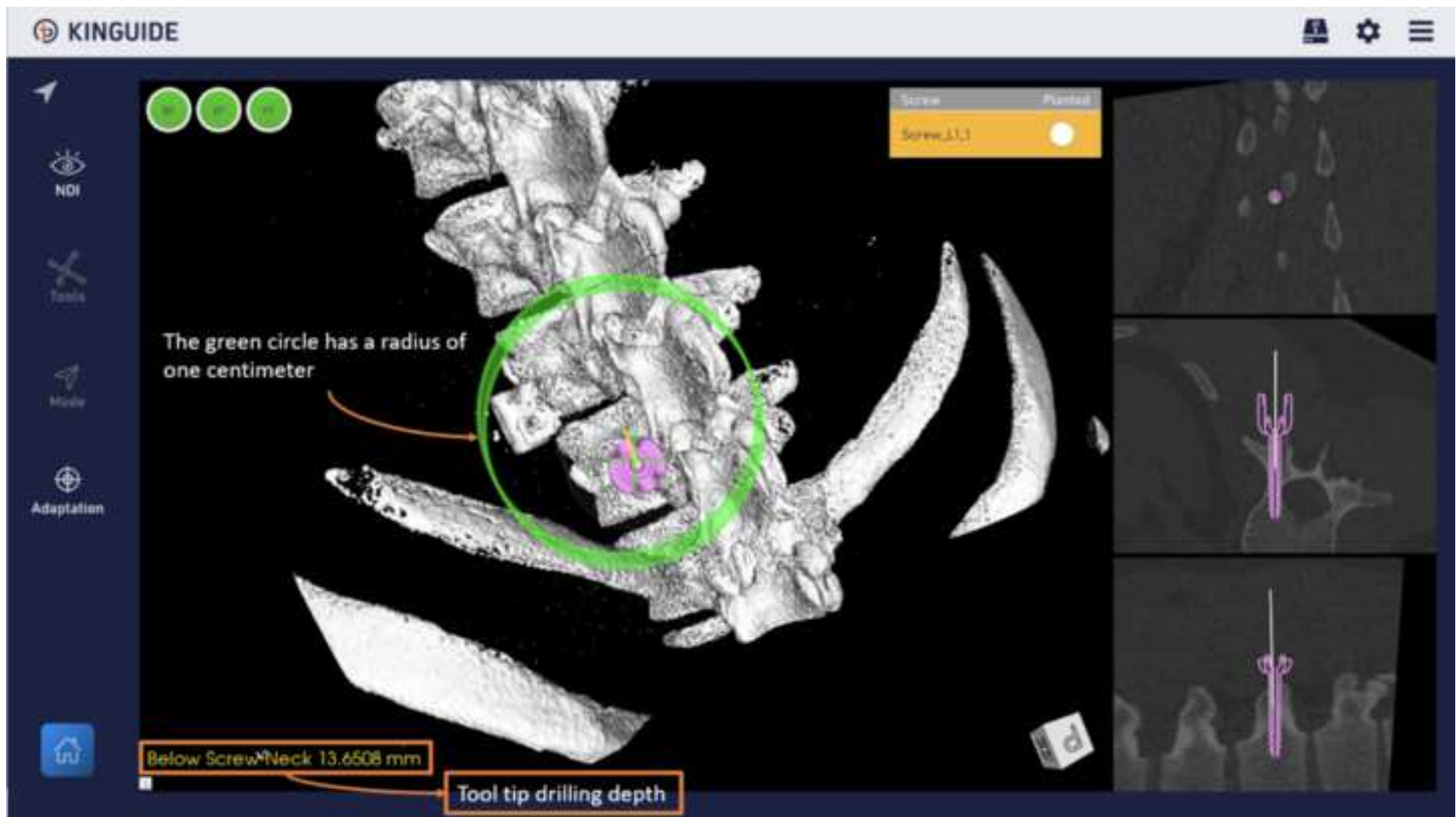
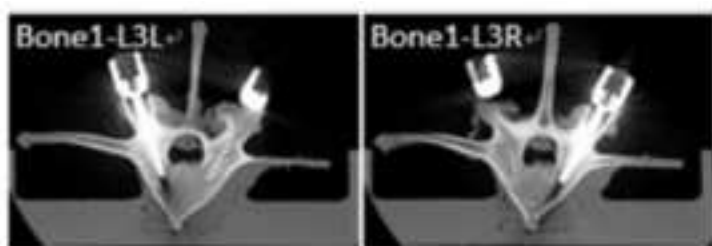


Figure 5

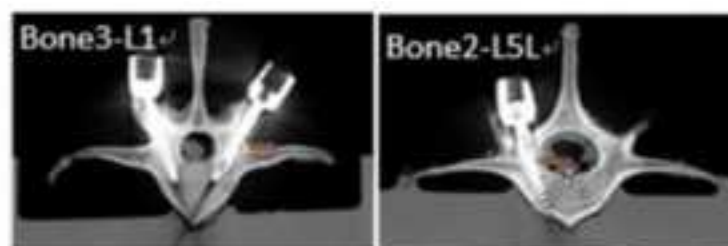




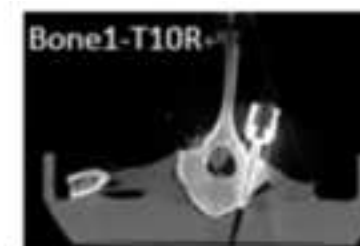




(a)



(b)



(c)

Name	Company
Dynamic reference frames	POINT
FF tool kit:	
1.Connecting Rod	
2.Combination clamps	
3.Multi-pin clamps	
4.Schanz screw	POINT
5.Spinous process clamp	
6.Open wrench	
7.Hexagonal wrench	
Handpiece	POINT
Handpiece holder	POINT
Handpiece stand	POINT
K-pin	POINT
Optical tracker	NDI
Passive spheres	NDI
Probe	POINT
Sterile box	POINT
Sterile drape	POINT
Trocar	POINT
Workstation cart	POINT

**Editorial comments:** Please use the attached word document to make the following edits and track all your changes.

• **Protocol Highlight:** Please highlight ~2.5 pages or less of text (which includes headings and spaces) in yellow, to identify which steps should be visualized to tell the most cohesive story of your protocol steps.

- The highlighting must include all relevant details that are required to perform the step. For example, if step 2.5 is highlighted for filming and the details of how to perform the step are given in steps 2.5.1 and 2.5.2, then the sub-steps where the details are provided must be included in the highlighting.
- The highlighted steps should form a cohesive narrative, that is, there must be a logical flow from one highlighted step to the next.
- Please highlight complete sentences (not parts of sentences). Include sub-headings and spaces when calculating the final highlighted length.
- Notes cannot be filmed and should be excluded from highlighting.
- Please ensure that steps you highlight will be available for filming.

Response: The major protocol steps have been highlighted.

• **Results:** Significant portions show significant overlap with previously published work. Please re-write the entire representative results section to avoid this overlap (Please refer to the attached iThenticate report).

Response: The manuscript has been rewrote, thank you.