# Navigation Accuracy and Functional Acceptance of the Stryker® PROFESS™ System for Computer-Assisted Intranasal and Sinus Surgery: A Cadaver-Based Investigation

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**Abstract:**

The Stryker PROFESS System is a surgical, navigation software module for image-guided intranasal procedures and endoscopic sinus surgery. This system tracks and displays the intraoperative location of the tip of navigated surgical instruments relative to a pre-operatively acquired CT image. The PROFESS System is composed of proprietary software, sterile, single-use navigated surgical instruments (suction tools and frontal sinus seeker), registration stickers and frame, patient tracker, and an adaptor cable. A computer platform (Stryker ADAPT®, Stryker NAV3® or Stryker NAV3i®) integrates the PROFESS System. The current cadaveric study was conducted in a simulated surgical setting to qualitatively validate the accuracy requirements and functional acceptance of the PROFESS System. Seven experienced ear, nose, and throat surgeons, some with specializations in rhinology, were recruited for this investigation. They each performed intranasal and sinus surgery, guided by the PROFESS System, on five undissected cadaver specimens (1 side/surgeon). Qualitative evaluation of user needs was validated by surgeon ratings (Likert Scale of 1-5) for accuracy, line of sight (accessibility) for each individual anatomic landmark, suction instrument functionality, and compatibility with current handheld instrumentation and conventional endoscopic operative techniques. Accuracy was evaluated by visual comparison between endoscopic images and the navigation display on registered CT. Line of sight was evaluated by verifying that the PROFESS System was able to the track the tip of the navigated surgical instruments for each specific, pre-determined anatomical landmark. Functional acceptance of PROFESS System tools was qualitatively validated by performing simulated surgical scenarios. Validation of accuracy and line of sight for the PROFESS System with respect to individual anatomical landmarks for intranasal and sinus procedures was confirmed by data that showed high surgeon rating scores in the range of 4.42-4.99. A high level of satisfaction with the PROFESS System was also expressed by surgeons in response to post-procedure questions regarding user needs for accuracy and line of sight of anatomical landmarks (average ratings of 4.86-5.0), suction functionality of tools (average rating of 5.0), and compatibility with handheld endoscopic instruments and conventional operative techniques (average ratings of 4.57-5.0). On the basis of the qualitative data collected from the current cadaveric study, it is reasonable to conclude that accuracy, line of sight of anatomical landmarks, and functional acceptance of the PROFESS System have been validated.

## Introduction:

Several surgical techniques have historically been effective for treatment of patients with sinus disease. These consist of conventional, non-endoscopic, external and intranasal surgical procedures with direct or microscopic visualization. Development of endoscopic surgical procedures and novel image-guided

surgery (IGS) has transformed the diagnosis and treatment of patients with paranasal sinus disorders[1]. In addition, the American Academy of Otolaryngology endorses the intraoperative use of IGS in appropriately selected cases to assist the surgeon in clarifying complex anatomy during sinus and skull base surgery[2]. Since its introduction in the United States in 1984, functional endoscopic sinus surgery (FESS) has become one of the most frequently performed surgical procedures in otolaryngology[3]. Indications for this procedure vary from less complicated cases of chronic sinusitis to multiple disorders affecting the paranasal sinuses, anterior and middle bases of the skull, and orbit[4]. Infectious forms of sinusitis are a common disorder that can often be successfully treated with antibiotics, anti-inflammatory, and topical therapies. However, refractory or recurrent sinusitis may necessitate FESS for more effective treatment. It has been estimated that 350,000 sinus surgeries are conducted annually in the United States with a yearly per capita incidence of 0.92 in 1000 in Medicare patients[5].

Increased use of FESS accompanied by the complex anatomy of the sinuses and skull base, proximity of critical structures (eye and brain) to the surgical field, and deformation in anatomical landmarks due to tumors or revision surgery have raised concern about intraoperative complications. Although the rate of major intraoperative complications associated with FESS is reported to be low (0.3-3.0%), intracranial and orbital penetration have resulted in catastrophic adverse events[6]. Orbital hematoma, vision changes, cerebrospinal fluid leak, blindness, intracranial damage, and death have been documented as major complications of FESS[1, 3, 6]. Minor complications of FESS include anosmia/hyposmia, periorbital ecchymosis, orbital emphysema, and epistaxis[3]. Preoperative and perioperative strategies have been proposed to reduce complications of FESS. Preoperative understanding of normal variants in skull and orbital anatomy via radiographic imaging and patient education about potential complications has been recommended. Suggested perioperative measures included optimizing visualization of the endoscopic surgical field and the use of image guidance systems to better define the boundaries of the surgical field and localization of vital structures[7].

Stereotactic IGS, also referred to as computer-assisted surgery (CAS), is a methodology that correlates anatomy in the operating field to computerized tomography (CT) and in some cases magnetic resonance imaging (MRI) data, based upon anatomic landmarks, or fiducial markers. This provides the surgeon with accurate boundaries of the surgical field and location of juxtaposed normal landmarks and critical structures[8]. Navigation accuracy is contingent upon the IGS registration process that establishes the correlation between specific landmarks and stored imaging data. Several registration techniques have been proposed, including the use of external fiducial markers, anatomical landmarks, or contour-based registration. Surface registration that utilizes unique facial contours reduces the preparation time of conventional registration and is clinically convenient[3, 8]. Recent survey data on the use of IGS have shown that surgeons, particularly otolaryngologists and rhinologists, routinely use this technology for FESS[5]. It is generally agreed that IGS can effectively orient the surgeon to the anatomy of the operating field for FESS procedures and provide additional support or validation for challenging surgeries with extensive mucosal disease, altered anatomy, a hemorrhagic endoscopic field, revision surgery, and/or sinonasal neoplasms. These challenging conditions often pose the greatest risk for major complications and may result in incomplete or suboptimal surgery with suboptimal outcomes or the need for revision

surgery. The use of IGS for FESS procedures has been proposed to reduce surgical complications and improve clinical outcomes[5].

The Stryker PROFESS System is a surgical, navigation software module for image-guided intranasal procedures and endoscopic sinus surgery. Specific examples of intranasal and sinus surgery procedures supported by the PROFESS System are FESS, including maxillary, ethmoid, sphenoid, and frontal sinus surgery and inferior, middle, or superior turbinate surgery. The system tracks and displays the intraoperative location of the tip of navigated surgical instruments relative to a pre-operative acquired series of CT images. The PROFESS System is comprised of proprietary software, sterile, single-use navigated surgical instruments (suction tools and a frontal sinus seeker), registration stickers and frame, patient tracker, and an adaptor cable. A computer platform (Stryker ADAPT, Stryker NAV3 or Stryker NAV3i) integrates the PROFESS System. The current cadaveric study was conducted in a simulated surgical setting to validate the accuracy requirements of the PROFESS System through qualitative assessment of surgeon needs and functional acceptance of the PROFESS tools. Qualitative evaluation of user needs was validated by surgeon ratings for a. accuracy, b. line of sight (accessibility) for each specific, pre-determined anatomical landmark, c. suction function of tools, and d. compatibility with conventional endoscopic operative techniques and other handheld devices. Accuracy was evaluated by visual comparison of endoscopic images with the navigation display. Functional acceptance of PROFESS tools was qualitatively evaluated and validated by otolaryngology surgeons who performed simulated surgical scenarios.

## Materials and Methods:

### Investigational Site and Investigators

Validation testing for navigation accuracy and functional acceptance of the Stryker PROFESS System was conducted at the Texas Health Resources Presbyterian Hospital, Minimally Invasive Technology Center, Dallas, Texas. The surgical suite was arranged for typical FESS procedures with respect to relative position of surgeon, patient, and operating room table. Video equipment, fluorescent ceiling lights, operating room light, Stryker endoscopy equipment, and a Mayo stand with standard intranasal and sinus surgery instruments were available. Since cadaver specimens were used, the procedure was non-sterile. Components of the PROFESS System used in this study are listed in Table 1 and shown in Figure 1. Hardware components are listed in Table 2. Seven ear, nose, and throat (ENT) surgeons were recruited as investigators for this study.

Table 1. Components of PROFESS System

| Test Object | Description |
|---|---|
| Stryker ADAPT Platform | Cart platform for PROFESS Software |
| PROFESS Software | PROFESS software application |
| PROFESS Curved 70° Suction | PROFESS tools |
| PROFESS Curved 90° Suction | |
| PROFESS Straight Suction | |
| PROFESS Frontal Sinus Seeker | |
| PROFESS Registration Kit | KIT package |
| -PROFESS Patient Tracker | |
| -PROFESS Registration Stickers | |
| -PROFESS Adaptor Cable | |

Table 2. Hardware Components used with PROFESS System

| Hardware Components | Description |
|---|---|
| Endoscope and video equipment | Standard equipment for FESS cases |
| Suction equipment | Standard equipment for FESS cases, to be connected to the suction tools |

Figure 1. Images of Components of PROFESS System

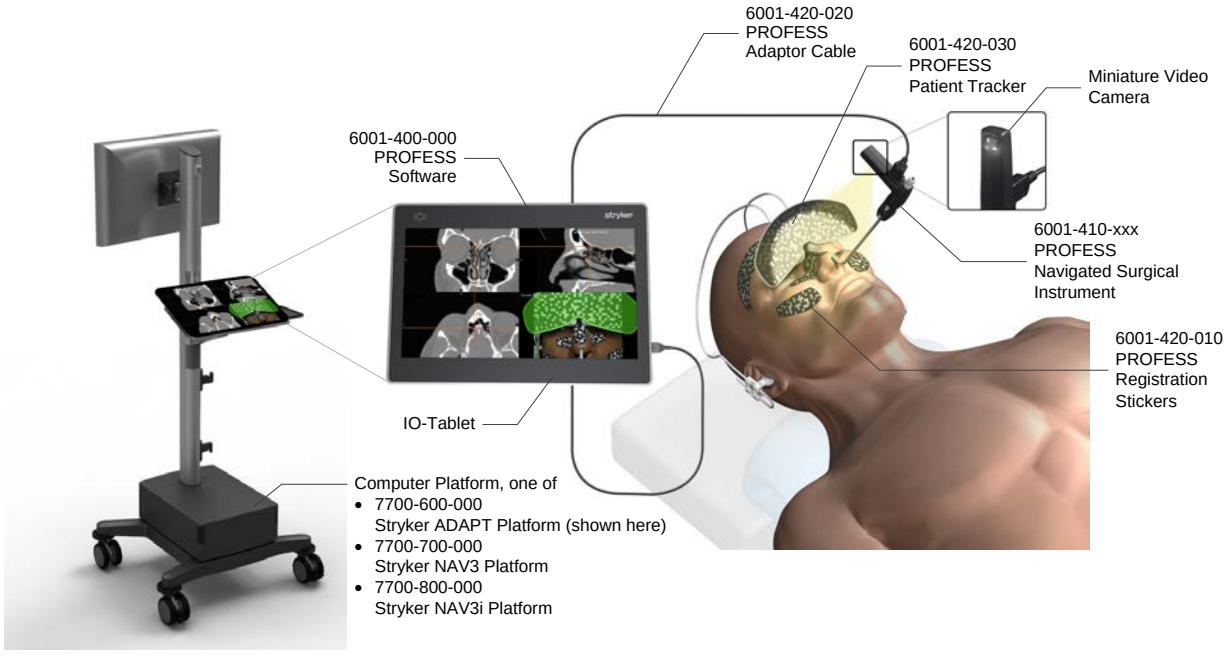
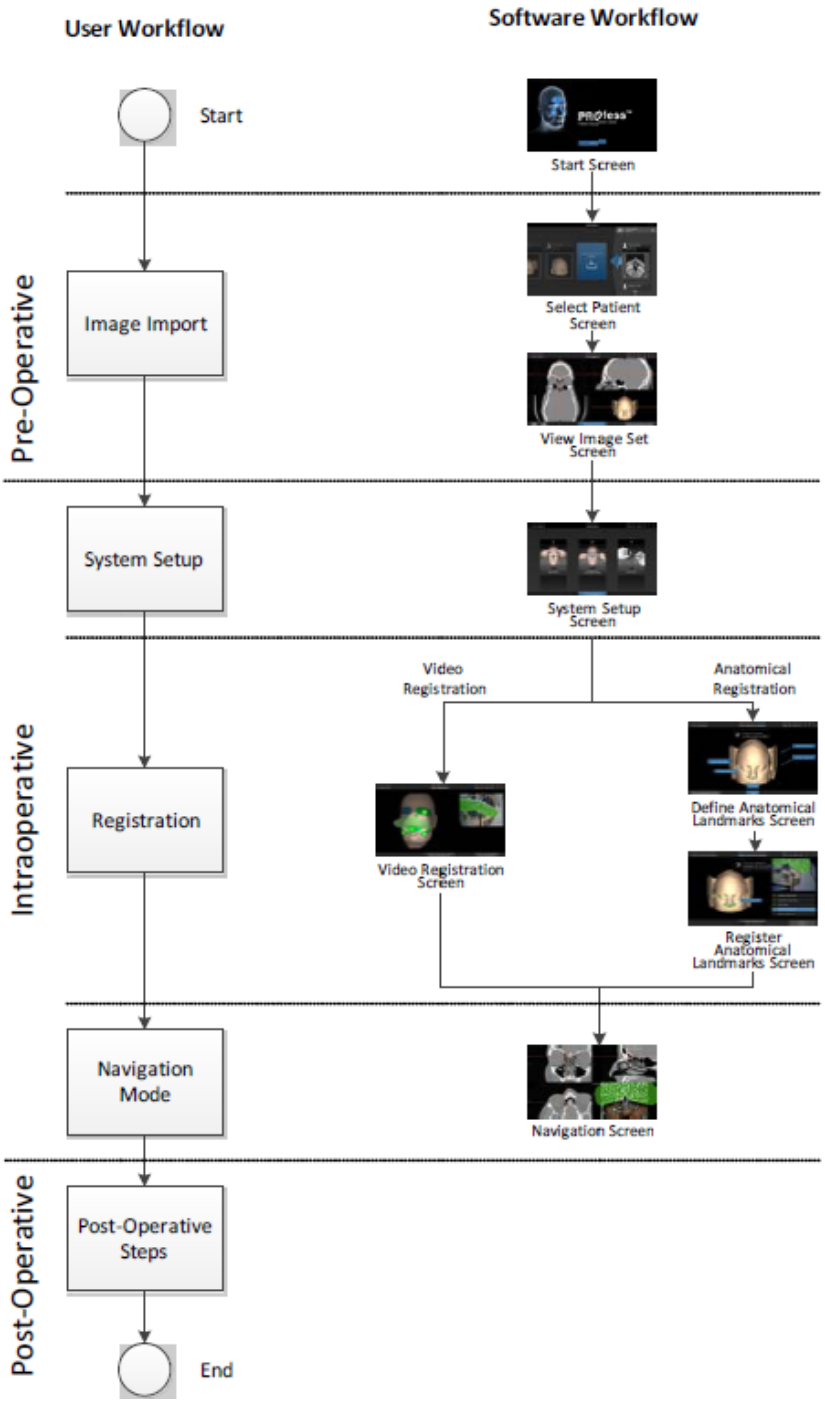


Figure 2. User and Software Workflow for PROFESS System



**Experimental Specimens and Rationale for Surgeon and Specimen Sample Size**

Five cadaver specimens with small to large head dimensions were selected to represent the expected variance in patient population. The head breadth varied in the range 133.1mm - 154.2mm and the distance of ear to nose varied in the range 96.9mm – 104.1mm. The measurements for each specimen are shown in Table 3. To minimize distortion of the face and nose, all requested specimens were stored in the supine position. The validation testing was conducted with 7 surgeons of different backgrounds and experience levels to reflect variability in surgical experience. Since both the specimens and surgeons covered the expected variance in patient and surgeon population the sample size is sufficient.

**Pre-Procedure Training of Surgeon Investigators**

Prior to simulated surgery on the cadaver specimens, the 7 surgeon investigators were trained on the Stryker PROFESS System. Training was performed on a test phantom head with the PROFESS System. A Stryker representative coordinated the training program.

**Validation Test Procedure**

After completion of training on the PROFESS System, validation test sessions were initiated under the guidance of a facilitator and with the assistance of an observer who was responsible for taking notes on each procedure. All sessions were recorded via video and audio to confirm aspects of data analysis. Each surgeon performed intranasal or sinus surgery on the right or left side of one of the cadaver specimens. The workflow for the PROFESS surgical procedure is shown diagrammatically in Figure 2 and consisted of the following steps:

1. Pre-operative import of the CT image set, acquired from scan of original cadaver specimen, to the PROFESS software

2. Operating suite preparation

3. Cadaver specimen preparation with application of PROFESS registration stickers to the face, assembly and placement of PROFESS patient tracker on the head, and connection of navigated surgical instruments to the computer platform with a PROFESS adaptor cable

4. Video registration and anatomical registration for determination and orientation of the cadaver reference frame relative to the CT image set coordination system

5. Navigation surgical mode with surgeon use of conventional surgical instruments, microscopes, or endoscopes to perform intranasal or sinus surgery; debris and fluid removal with Stryker PROFESS suction tools; in addition to direct or endoscopic visualization of the surgical site, surgeon localization of the position of the tip of PROFESS navigated surgical instruments relative to the CT image via PROFESS software

6. Post-operative removal of the PROFESS patient tracker from the head and PROFESS registration stickers from the face

7. Post-procedure questions for each surgeon regarding fulfillment of user need for accuracy, accessibility of anatomical landmarks, suction function of tools, compatibility with conventional operative technique and other devices, and intended use/indications for use

Steps 1-3 were performed by the Stryker facilitator, steps 4-6 by the surgeon, and step 7 was administered by the Stryker facilitator to each surgeon.

For the video and anatomical registration processes in steps 4-6, each surgeon navigated with one of the PROFESS tools (surgeon choice) to the following defined anatomical landmarks: anterior wall of ethmoid bulla, ethmoid bulla, posterior wall of ethmoid, roof of ethmoid (foveo ethmoidalis), face of sphenoid, posterior wall of sphenoid, naso-lacrimal duct, lamina papyracea, lower frontal sinus/frontal recess, maxillary ostiuma, and posterior wall maxillary sinus. Correct placement of the tool tip with respect to each landmark was corroborated by endoscopy. Accuracy was determined by comparison of the true position of the tool tip with the tool position displayed on the CT image by the PROFESS System. The following subjective ratings were provided by each surgeon during the FESS procedure:

1. Accuracy of tool tip position rated with respect to the surgeon's requirements for the specified indications for use

2. Line of sight (accessibility) for each anatomical landmark

Subjective ratings by each surgeon were acquired by the Likert Scale. Likert Scale ratings are as follows: 1. disagree, 2. somewhat disagree, 3. neither agree nor disagree, 4. somewhat agree, or 5. agree. Acceptance criteria were prospectively established to demonstrate that accuracy and line of sight of the PROFESS System were compatible with the indications for use. These criteria were that 80% of the average of the surgeon ratings must fall within the range of 3.0-5.0.

In step 7, the post-procedure questionnaire that addressed fulfillment of user needs was administered to each surgeon. Subjective ratings for this questionnaire were also captured by the Likert Scale. Acceptance criteria were prospectively developed to show that the PROFESS System fulfills the needs of the surgeon. These criteria were that 80% of the surgeon ratings must occur within the range of 3.0-5.0.

Table 3. Measured Head Sizes of Cadaver Specimens

| Specimen ID | Head breadth (mm) | Ear-nose saddle distance (mm) |
|---|---|---|
| 63057 | 133.1 | 96.9 |
| 61460 | 146.9 | 94.2 |
| 621490 | 147.4 | 97.8 |
| 60452 | 152.4 | 102.8 |
| 62081 | 154.2 | 104.1 |

**Results:**

Table 4 presents the average of surgeon ratings for accuracy and line of sight with respect to each of the 11 pre-determined anatomical landmarks (critical and non-critical). The data indicates that all averaged ratings were above 4.4 (range 4.42-4.99). It should be noted that reproducibility of the placement of the patient tracker was substantiated by the averaged surgeon accuracy rating of 4.88 (refer to row C).

Table 4. Averaged Surgeon Ratings for Accuracy and Line of Sight of All Anatomical Landmarks

| | Anatomical landmark | | Anterior Middle Turbinate | Ethmoid Bulla | Posterior Wall of Ethmoid | Roof of Ethmoid (Fovea) | Face of Sphenoid | Posterior Wall of Sphenoid | Naso-Lacrimal Duct | Lamina | Lower Frontal Sinus | Maxillary Ostia | Posterior Wall Maxillary Sinus | **Average** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | - |
| | Critical landmark | | N | N | Y | Y | N | Y | Y | N | Y | N | N | - |
| A | All registrations (video and anatomical) and tracker off/on | **Accuracy** | 4.71 | 4.91 | 4.67 | 4.65 | 4.63 | 4.69 | 4.73 | 4.71 | 4.80 | 4.86 | 4.52 | **4.72** |
| | | **Line of sight** | 5.00 | 4.86 | 4.98 | 5.00 | 5.00 | 4.94 | 4.98 | 4.89 | 4.98 | 4.94 | 4.90 | **4.95** |
| B | Video registrations and tracker off/on | **Accuracy** | 4.62 | 5.00 | 4.83 | 4.86 | 4.81 | 4.97 | 4.89 | 4.86 | 4.97 | 4.95 | 4.86 | **4.87** |
| | | **Line of sight** | 5.00 | 4.76 | 4.97 | 5.00 | 5.00 | 4.97 | 5.00 | 4.81 | 4.97 | 4.90 | 4.86 | **4.93** |
| C | Tracker off/on | **Accuracy** | 4.64 | 5.00 | 4.79 | 4.86 | 4.86 | 5.00 | 4.93 | 4.87 | 4.93 | 5.00 | 4.86 | **4.88** |
| | | **Line of sight** | 5.00 | 4.86 | 4.93 | 5.00 | 5.00 | 4.93 | 5.00 | 4.79 | 4.93 | 4.86 | 4.79 | **4.92** |
| D | Anatomical registrations | **Accuracy** | 4.86 | 4.79 | 4.29 | 4.14 | 4.36 | 4.00 | 4.36 | 4.50 | 4.36 | 4.71 | 4.29 | **4.42** |
| | | **Line of sight** | 5.00 | 5.00 | 5.00 | 5.00 | 5.00 | 5.00 | 4.93 | 5.00 | 5.00 | 5.00 | 4.93 | **4.99** |

Table 5 demonstrates the ratings of each surgeon for accuracy and line of sight that were averaged over all landmarks. The percentage of surgeons with ratings in the range of 3.0-5.0 is also shown. With the exception of one surgeon, with an accuracy rating of 2.98 for anatomical registration, the data revealed that all averaged ratings were above 4.2 (range 4.27-5.00). The percentage of surgeons with ratings of 3.0-5.0 was above 80% (range 86-100%). Replication of the placement of the patient tracker was confirmed as 100% of the surgeons rated the accuracy above 4.6 (range 4.67-5.00) for the average of all landmarks. Overall, the data in Tables 5 and 6 met the validation criteria for navigation accuracy and line of sight for the PROFESS system.

Table 5. Ratings of Each Surgeon for Accuracy and Line of Sight Averaged Over All Landmarks

| | Surgeon | S01 | | S02 | | S03 | | S04 | | S05 | | S06 | | S07 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Accuracy | Line of sight | Accuracy | Line of sight | Accuracy | Line of sight | Accuracy | Line of sight | Accuracy | Line of sight | Accuracy | Line of sight | Accuracy | Line of sight | % of Surgeons rated with 3, 4, or 5 |
| A | All registrations (video and anatomical) and tracker off/on | 5.00 | 4.81 | 4.92 | 4.96 | 4.65 | 4.99 | 4.62 | 5.00 | 4.27 | 4.92 | 4.75 | 4.99 | 4.88 | 4.97 | 100% |
| B | Video registrations and tracker off/on | 5.00 | 4.77 | 4.90 | 4.93 | 4.83 | 4.98 | 4.66 | 5.00 | 4.78 | 4.89 | 4.89 | 5.00 | 4.94 | 4.98 | 100% |
| C | Tracker off/on | 5.00 | 4.63 | 4.84 | 4.96 | 4.79 | 4.96 | 4.67 | 5.00 | 4.88 | 4.89 | 4.95 | 5.00 | 4.88 | 4.96 | 100% |
| D | Anatomical registrations | 5.00 | 4.95 | 4.96 | 5.00 | 4.47 | 5.00 | 4.44 | 5.00 | 2.98 | 4.96 | 4.47 | 4.96 | 4.76 | 5.00 | 86% |

Table 6 discloses the average rating of all seven surgeons with respect to post-procedure questions on user need for accuracy and line of sight, suction function of tools, and compatibility with conventional endoscopic operative technique and other handheld devices. With respect to questions 1-4 on accuracy and line of sight for navigation, all surgeons responded with ratings in the range of 3.0-5.0 and average ratings of 4.86-5.0. Suction control and function of all three tools used during the simulated surgeries and at the end of testing showed a high level of satisfaction with all surgeons responding to question 5 with a rating of 5.0. In response to questions 6 and 7, all surgeons agreed that the PROFESS System is compatible with conventional operative technique and other surgical devices with average ratings of 4.57-5.0. These questionnaire data further support navigation accuracy and line of sight for the PROFESS system as well as surgeon acceptance of functionality.

Table 6. Averaged Surgeon Ratings for Post-Procedure Questionnaire

| # | Question | # of surgeons | Average rating | % of surgeons who rated with a 3,4, or 5 |
|---|---|---|---|---|
| 1 | I was able to navigate to all landmarks with acceptable accuracy and line of sight | 7 | 5.00 | 100% |
| 2 | Navigated Instruments feel and perform very similar to the standard instruments | 7 | 4.86 | 100% |
| 3 | Tool position can be identified relative to the CT scan while tool is held steady | 7 | 5.00 | 100% |
| 4 | System accuracy is sufficient for intranasal and sinus surgery | 7 | 5.00 | 100% |
| 5 | Suction can be controlled sufficiently during the surgery | 7 | 5.00 | 100% |
| 6 | Tracking can be done under the standard lighting conditions needed for intranasal and sinus surgery procedures | 7 | 5.00 | 100% |
| 7 | Navigation equipment does not interfere with standard instruments and accessories used in intranasal and sinus surgery procedures | 7 | 4.57 | 100% |

The current statements in the Indications for Use were submitted to each surgeon for assessment and a response of “agree” or “disagree”. Five of the 7 surgeons agreed with the Indications for Use but also suggested additional indications such as orbital decompression endoscopy surgery, optic nerve decompression surgery, cerebrospinal fluid leak repair, and Eustachian tube dilation. One surgeon disagreed and recommended the addition of skull base surgeries. This surgeon also proposed deletion of “functional” (ESS instead of FESS) because it implied chronic sinusitis as the indication. Another surgeon did not give a rating but suggested additional indications of balloon dilation, dacro-cysto-rhinosotomy and use of the word “intraoperative” to confine the Indications for Use to the operating suite rather than office-based.

**Discussion and Conclusion:**

The Stryker PROFESS System is a surgical, navigation software module that is used in combination with a Stryker computer platform. It functions as an intraoperative guidance system to permit intranasal procedures and endoscopic sinus surgery. This system tracks and displays the intraoperative location of the tip of navigated surgical instruments (suction tools) relative to a set of CT images. The system can be used for intraoperative guidance relative to a rigid anatomical structure and supports endoscopic sinus surgery and intranasal procedures. The purpose of this cadaveric study was to validate the accuracy demands of the PROFESS System through qualitative analysis of surgeon requirements and functional acceptance of the PROFESS tools. Validation of accuracy and line of sight for the PROFESS System with respect to individual anatomical landmarks for FESS were achieved by obtaining data that showed high rating scores by surgeons for these endpoints. A high level of satisfaction with the PROFESS System was

also expressed by surgeons in response to post-procedure questions on user need for overall accuracy and line of sight, suction functionality of tools, and compatibility with conventional operative techniques and other devices. On the basis of the qualitative data in the current cadaveric study, it is concluded that the accuracy and functional acceptance of the PROFESS System have been validated.

It is important to emphasize the video pattern recognition as one of the key features of the PROFESS System for sinus or intranasal procedures. This technology is based on the use of live video images captured by the miniature video camera mounted on each of the PROFESS Navigated Surgical Instruments. During registration of the patient, the PROFESS software is able to recognize the PROFESS Registration Stickers in the video image to compute the location of surface points on the PROFESS Registration Stickers relative to the PROFESS Patient Tracker. The surface points are used to register the patient relative to a coordinate system which is fixed to the 3-dimensional reconstruction of the CT image set. Once the patient has been registered, the camera continues to capture live images that include the PROFESS Patient Tracker. The captured images are processed by the PROFESS software for localization and tracking of the PROFESS Navigated Surgical Instrument relative to the PROFESS Patient Tracker. As demonstrated in the current cadaver validation study, the video pattern recognition feature of the PROFESS system is a major factor underlying accurate patient registration and the surgeon's accuracy and line of sight for FESS. Surface registration that utilizes unique facial contours has also been shown to reduce the preparation time of conventional patient registration and is clinically convenient[3, 8].

The complicated and variable anatomy of the sinuses and cranial base has been documented to present significant challenges to the surgeon's orientation during FESS. The close anatomical relationship of critical organs, such as the orbit and brain, to the operative field increases the risk of minor and major complications attributable to FESS[1, 3, 6]. In an effort to more accurately evaluate and navigate the anatomical boundaries of the operative area of the sinuses and skull base regions and possibly help to mitigate the risk of complications of FESS, the use of IGS has been recommended[7, 8]. Based upon the high level of surgeon satisfaction with the accuracy and functional acceptance of the PROFESS System in the present cadaveric validation study, this computer-assisted surgical navigation module may validate intraoperative localization, improve surgical precision and possibly reduce avoidable complications in patients that require sinus and/or intranasal procedures.

**Stryker part numbers used:**

6001-400-000, 6001-410-070, 6001-410-090, 6001-410-000,

6001-410-100, 6001-420-010, 6001-420-030,

6001-420-020, 7700-600-000

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