Experimental Evaluation of PARSISS Image Guided Surgery System

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A B S T R A C T

Purpose: In this report, a thorough validation of PARSISS Image Guided Surgery has been presented.

Methods: Different experiments have been designed to evaluate Parsiss navigation system under three main scopes: first, a phantom study using a sophisticated precise phantom with 732 landmarks was constructed by 3d printing with layers of 16 micron thickness and 0.1 mm precision; second, performing preclinical cadaver experiment with titanium placed markers; and third, clinical evaluation which was carried out on 957 cases from 2010 to 2014.

Results: Results obtained from three evaluation methods showed that the system was found reliable and usable. Briefly, the average registration error in PARSISS precise phantom test was reported lower than 2 mm this which is clinically acceptable and reasonable in neurosurgery and ENT surgeries. In clinical evaluation, surgeons approved the accuracy and reliability of the system in thorough clinical evaluation in 94% of cases of 957 patients.

Conclusion: In this study, the results of all three approaches were positive and reliable. Especially, evaluations using a large number of patients showed that the PARSISS surgical navigation system has shown high level of reliability in clinical procedures.

1. Introduction

Image Guided Surgery (IGS) system represents a rapidly advancing technology among the minimally invasive surgical procedures. This technology had been used in 1990s for the first time [1, 2]. In the last decade, its use has become increasingly common to assist complex surgeries [3-8]. This system works such as a global positioning system [9] and shows the position and orientation of the instruments in 2D and 3D images. The major approach of the navigation system is to use advanced methods for analysis and reconstruction of the information produced from prevalent medical imaging modalities such as MRI and CT scans on one hand and the 3D position information of surgery tools from accurate noncontact tracking systems on the other hand, so that it gives a virtual vision of the surgery area where a straight vision is not possible for the surgeon. Base on the patient preoperative images, virtual anatomy of the patient is reconstructed and when the surgeon moves his/her instrument, the position of the instrument is measured and monitored real-timely. In this case, by easing the usage of image information and following the

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position of the instrument instantly, the system could increase the accuracy and quality of the surgery more than traditional approach [6]. Figure 1 shows the overall workflow of the system.

The surgical navigation system improves accuracy and reduces intervention time, morbidity, and intensive care and hospital costs [10-13]. Today, IGS is used to help surgeons to plan the surgery by providing accurate information about the anatomy, and it also enables minimally invasive interventions, since the intraoperative images can be used interactively as a guide [2].The IGS system is also used in the fields of sinus surgery, skull base surgery, pituitary and brain surgery, biopsy, deep brain stimulation, spine surgery, and orthopedic surgery [3, 5, 10, 14, 15].

2. Materials and Methods

2.1. PARSISS Navigation System

PARSISS (Parseh Intelligent Surgical System, Tehran, Iran) navigation system introduced a self-designed navigation system that can be used in ear, nose, and throat (ENT) surgeries and neurosurgeries at 2010.The system has a user-friendly graphical user interface so that the user can access all the required features. The main features of the system are the possibilities of using different medical imaging modalities and making fused images based on them, surgery preplanning for a better understanding of complex anatomy, the easy and precise registration in addition to lots useful features during navigation. The system is powered by a sophisticated volume and surface rendering engine to create attractive 3D models that could be manipulated in real-time response.

PARSISS offers two different models of navigation system: ImageVision^{TM} (IV) and OpticVision^{TM} (OV). The IV system is applicable in ENT surgeries, however the OV system is applicable in both ENT surgeries and neurosurgeries. It must also be mentioned that the system has got all the necessary certificates such as CE (2195), ISO 13485, IEC 60601-1, and IEC 60601-1-2.

2.1.1. OV System

One of the surgical navigation systems offered by PARSISS Company is the OV system (Figure 2 (a)), which is powered by the infrared tracker with no sensitivity to visible light. The various software features, high accuracy, presence of planning facilities including segmentation, automatic multimodality image fusion, and generation of composite models have made this system as an ideal navigation system for neurosurgeries and ENT surgeries.

The sophisticated navigation tools in addition to conventional surgical tool aided by general detachable markers enable the surgeon to access any anatomical structure as shown in Figure 2(b).

2.1.2. IV System

PARSISS offers another modern surgical navigation system, called the IV which is powered by visible range stereo camera tracking system based on check board pattern markers as shown in Figure 2(c). The IV system

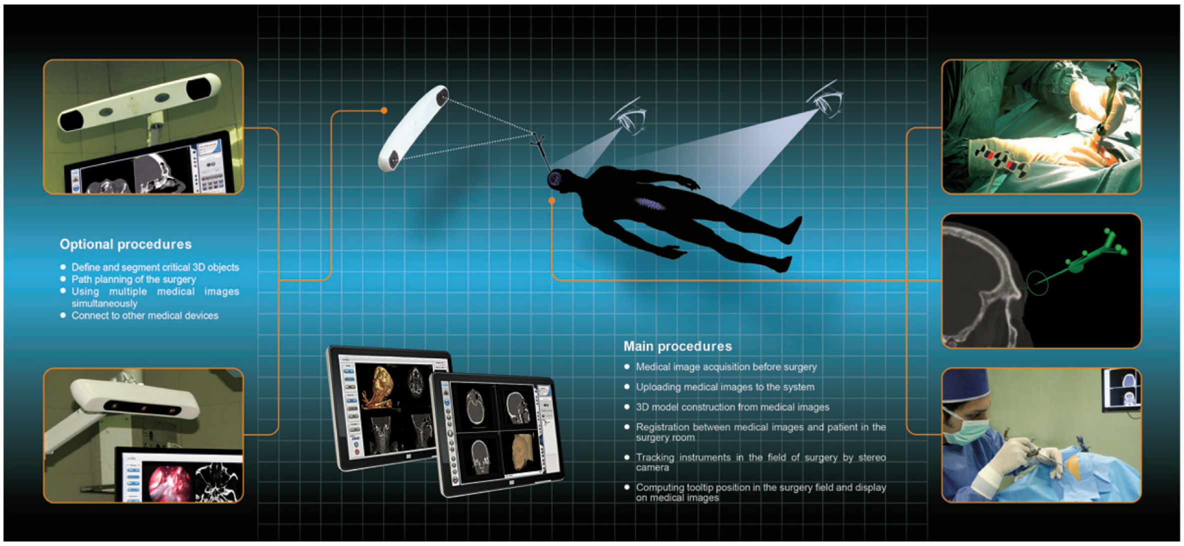
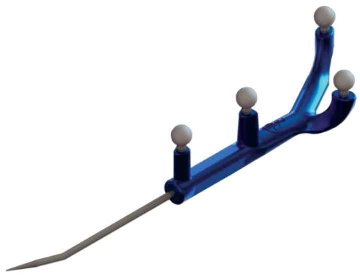


Figure 1. Overall IGS workflow.

a



b

c

Figure 2. (a) OV System powered by infrared tracker used in neurosurgeries and ENT surgeries, **(b)** Sample of sophisticated surgery tool designed to reach frontal sinus easily, and **(c)** Check-board pattern used as tracking markers for detachable adaptors.

has a wide range of facilities to perform a supersensitive and accurate surgery. The simplicity of the system and the markers, the various software features, and the high accuracy make IV as an appropriate option for ENT surgeries, which usually utilizes a headband as a minimal invasive patient reference.

2.2. Evaluation Strategies

PARSISS IGS was examined under the following three scopes to evaluate its benefits and usability: phantom tests, cadaver examination, and thorough clinical evaluation.

2.2.1. Phantom Test

A unique skull phantom was designed and fabricated as a reference for evaluation of the navigation system, as shown in Figure 3. To obtain DICOM images, CT scanning was performed using a multi-slice CT scanner, with slice thickness of 0.6 mm, tube current of 400 mA, and field of view including the entire head and mid-face. To achieve the best possible design, an extensive study was performed to gather the necessary information to keep the designed phantom similar to human skull. Subsequently, it led to the presence of numerous markers located at anatomically important places with provided accessibility of the markers to the surgeon. On the phantom face, 17 fixed fiducial points were embedded in the locations, which are most commonly used as anatomical landmarks, for registration in head and neck surgeries. I addition, the phantom is equipped with 732 intra cranial point for evaluation of target registration error in all cranial regions.

2.2.2. Preclinical Examination

Before clinical trial, preclinical tests were needed to ensure the safety and benefits. Simulated surgeries based on real situation were planned and performed on a cadaver in cooperation with forensic experts and ENT surgeons. It was performed according to the following step-by-step scheme:

- Choosing an appropriate cadaver with different anatomies for the endoscopic surgery performed by forensic experts and ENT surgeons
- Planting six titanium screws as fixed checkpoints on the cadaver
- Acquiring multi-slice CT scan (slice thickness = 0.625 mm)
- Performing endoscopic surgical procedure using the navigation system in an 8 hour session by an ENT surgeon on each cadaver
- Evaluating the surgery steps with the navigation system

The preclinical evaluation included facial surface landmarks, superficial landmark of sinus, and deep landmarks such as the fiber optic and the carotid of cadavers. For this purpose, after placing the surgery tool's tip on

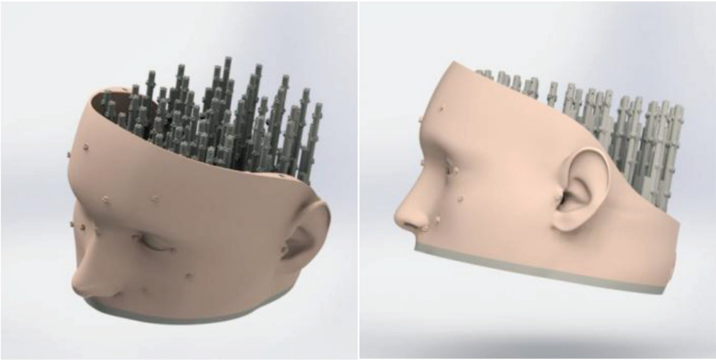


Figure 3. PARSISS Skull Phantom (PSP) consisting of 732 landmarks was designed for laboratory examination for simulation of all the internal areas of the skull and sinusoidal regions.

the considered accurate position, the distance between the tool's tip and the considered position was measured. In addition to these landmarks, 6titanium screws were planted before imaging on the bone tissues, which were clearly identifiable on the CT images of the cadaver. It was done for precision measuring during surgery.

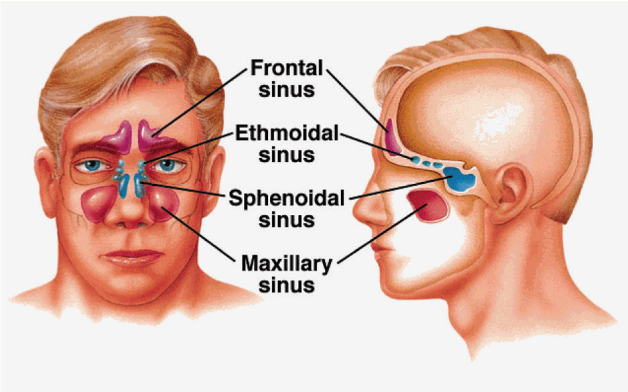
2.2.3. Clinical Evaluation

The clinical evaluation process was based on the European Union Annex X directive medical equipment and standard EN ISO 14155:2011. This evaluation was done for both IV and OV systems separately. A total of 957 patients were chosen by the surgeons based on standard indication of utilizing navigation in their surgeries, among which 583 (61%) were males and 374 (39%) were females, and their age-group ranged from 20 months to 72 years.

In the clinical evaluation stage, measuring all of the fiducial points would not be possible by the surgeon because of prolongation of the surgery duration of and the unconsciousness condition of the patient. Since the surgeon declare the results of his/her tests after the surgery in evaluating parameters: reliability, accuracy, and registration time as defined as below:

Accuracy: The most important task of the surgical operating system is to represent the location of the tool's point during surgery. In practice, the surgeons check the accuracy at well-known anatomical points and acts at unknown location based on system information. In this regard, the surgeon's point of view is requested after surgery about the system accuracy. In this case, the surgeon offered grades from 0 that means to "lack of accuracy" to 10 that means to "excellent accuracy."

Preparation Time: One of the most important conditions in the operating room is the minimum time required to start the system. In this regard, the surgeon's point of view is requested after every surgery about the time taken for system preparation, and the surgeon offered grades from 0 to 10, which means "very slow" to "very fast", respectively.



a

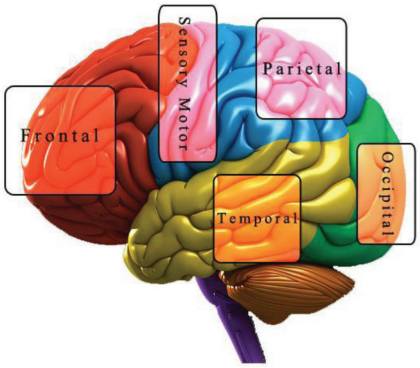


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Figure 4. PARSISS Skull Phantom (PSP) consisting of 732 landmarks was designed for laboratory examination for simulation of all the internal areas of the skull and sinusoidal regions.

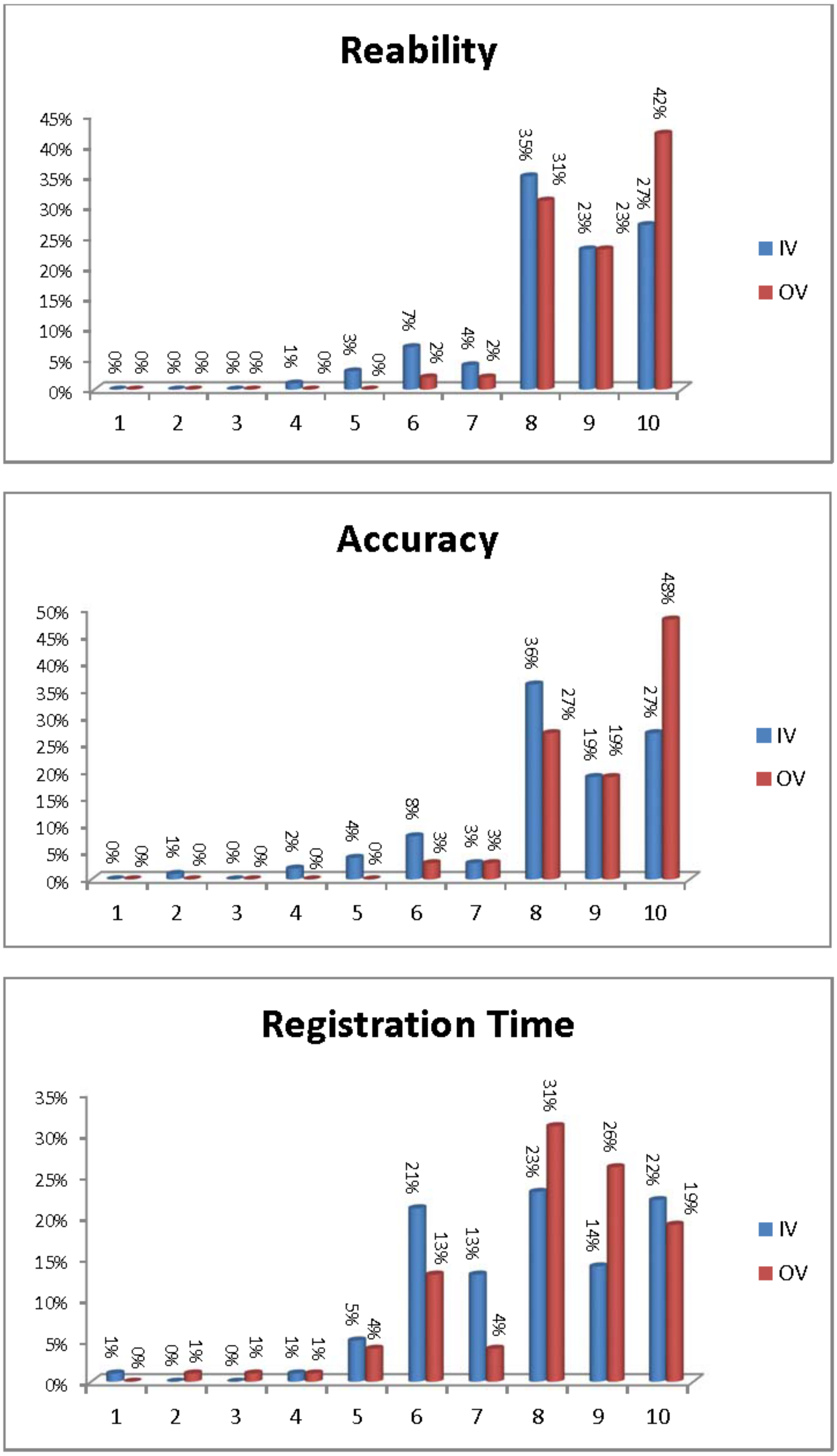

Figure 5. Quantitative evaluation of OV (623 cases) and IV (334 cases) in 957 clinical cases from diffrenet point of view: **(a)** accuracy; **(b)** preparation time, and **(c)** reliability. Number of cases versus score that score 1 means completely unacceptable and 10 means completely acceptable.

Table 1. The navigation Error in different head zone and anatomical area is presented. As the evaluation area is far from the face as a registration region, the navigation error increases.

Zone	Area	Number of evaluated points in region	Navigation Mean Error (mm)	
			OpticVision	ImageVision
Brain Zone	Frontal	12	1.575	1.33
	Temporal	12	2.371	2.14
	SensoryMotor	7	2	1.9
	Occipital:	6	3.571	3.74
	Parietal	12	3.305	3.67
sinusoidal Zone	Frontal	6	0.756	0.823
	Ethmoid	6	0.501	0.543
	Sphenoid	4	0.653	0.730
	Maxillary	8	0.795	0.879

Table 2. The average and variance of evaluated parameter in clinical examination. The score 1 means completely untrusted or unacceptable and 10 means completely acceptable or trusted.

Evaluated Parameter	Average ± Std (grade between: 1 -10)	
	OpticVision	ImageVision
Reliability	9.00 ± 1.01	8.48 ± 1.33
Accuracy	9.04 ± 1.09	8.33 ± 1.55
Registration time	8.06 ± 1.67	8.06 ± 1.67

Reliability: Finally, for utilizing the system in the operating rooms, achieving the surgeon's trust is very important and essential. Surgeons would use the system in surgeries only if they trust the system, which shall be achieved through a set of factors: the system's accuracy, the stability of system all times during surgery, the convenience in using the system and its tools, and availability of all required abilities. Again, the surgeon's response grades from 0 that means to "I don't trust at all" to 10 that equals to "I totally trust."

3. Results

3.1. Phantom Results

Frontal, ethmoid, sphenoid, and maxillary sinuses were considered as the desired regions for ENT surgery simulation in addition to cerebral regions specified by five different regions including frontal, temporal, parietal, and occipital lobes and sensory motor area as shown in Figure 4. The numbers of positions evaluated in these regions are specified in Table 1. The results demonstrated that the farther the registration points from the evaluation region leaded to the greater navigation error. The worst case was the occipital region which is the farthest anatomical area from the registration landmark.

3.2. Preclinical Results

About 69 points were checked for every system, and it was observed that there was less than 0.5 mm in 75% of the landmarks at axial, sagittal, and coronal view that was not significant from the surgeon's point of view; less than 2 mm error observed in 15% of the landmarks and more than 2 mm error in the rest of 10% landmarks. Due to these acceptable results in which the total error were generally lower than 2 mm, the performance of the system was approved acceptable at this level and following this permission for clinical tests was issued by the related authorities.

3.3. Clinical Results

The evaluation was done over 957 clinical cases in 41 hospitals by more than 60 surgeons from 2010 to 2014 in Iran. The quantitative evaluation of OV (623 cases) and IV (334 cases) was done under the following three viewpoints: accuracy, registration(or preparation) time, and reliability as shown in Figure 5. From the accuracy point of view, the surgeon indicated that the OV and IV system can be "well trusted" or "completely trusted" in 94% and 82% of the surgeries, respectively. From the preparation time aspect, the OV system was "quite fast" or "completely fast" in 76% of the situations and the IV in 59% situations. Regarding total reliability, the OV and IV system reached "well trusted" or "completely trusted" in 96% and 85% of the surgeries respectively. In overall, surgeons approved the accuracy and reliability of the system in 94% of cases.

From another point of view, as shown in Table 2, the average accuracy and reliability values were 9.01 ± 0.17 and 8.48 ± 0.21 from 10 for OV and IV systems (mean ± SE), respectively, which mean that the system is accurate and trustable from the surgeon's point of view and is also satisfactory.

4. Discussion

Surgical navigation helps surgeons to plan the location and precise size of the craniotomy flap and also to determine the relationships between the lesion and surgical approach to critical brain tissues in preoperative surgeries. Besides precise craniotomy, it also guides the surgeon to a subcortical lesion and assists in resection control (i.e., determining whether the intended resection has been accomplished).

In this study, the results of all three approaches were found positive and reliable. The phantom test results indicated that the navigation system had an acceptable functional performance. Quantitative evaluation of the landmarks with respect to various anatomic points of the brain showed system conformation to reality. The successful results of the cadaver tests, which were performed using well-known anatomical landmark and planted titanium landmarks in bone tissues for the accurate evaluation of the system, provided the necessary permissions for human clinical tests. In conclusion, results obtained from the different kinds of evaluations using a large number of patients and with the help of a performance ranking system on specific features, such as precision and reliability of the system, showed that the PARSISS surgical navigation system has a high level of reliability in clinical procedures. To sum up, it can be concluded that these systems are clinically efficient and reliable.

5. Conclusion

Different kinds of evaluation results obtained in this study confirm the efficiency and usefulness of navigation systems and its growing usage trends indicates this fact. Further studies using large number of human subjects and usage of these systems in more number of surgeries will help in increasing the trust in these systems by the medical society. The system is competitive to other available commercial systems from the point of view of the provided technical abilities and facilities.

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