Neuronavigation System

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1. INTRODUCTION

In the past decade, image-guided surgical systems have been developed to assist surgeons in performing surgery more safely, effectively, and cost effectively. Although most systems are designed originally for neurosurgical use, they may be applicable to other surgical specialties including orthopedic surgery, otorhinolaryngology and urology. Image-guided surgery allows surgeons to localize the lesion being treated more accurately, to determine the full extent of the lesion, and to choose a safe surgical approach associated with reduced surgical morbidity. The utility of image-guided surgical system is increasing (Hall et al., 2000).

2. OBJECTIVE

To assess the safety, effectiveness and cost implications of the use of the neuro-navigation system in orthopedics, neurosurgery and ENT surgery.

3. TECHNICAL FEATURES

Surgical navigation system is a system that processes medical images by computer graphics and image processing techniques, reconstructs 2-D or 3-D medical image models. It builds a real-time loop among the eyes of doctor, the surgical device and the anatomical parts of patients by several space localization techniques, to be able to display the localization of surgical devices in real time. The key techniques include localization in space, image processing and displaying technique, system registration techniques and anatomical parts location techniques (Hao and Zhu, 2004).

The detector is intimately linked to a computer that analyzes information collected. Computer programming is done so that instrument and any other item in the surgical field "marked" with infrared emitters can be tracked. Furthermore, it is programmed to recognize the shape and position of any particular instrument, pointer or prosthesis. The accuracy is usually within 0.5-1.0mm, and the angular accuracy is typically within 1°. Interaction is simultaneous. The position of the markers can be tracked relative to each other.

Registration can be done using an instrumented pointer to specify the location of the landmarks of each bone so the computer can track its position, surfaces, and rotation- alignment feature.

The navigation system used in orthopedics can be characterized as imageless, computed-based tomography (CT), or fluoroscopy-based, while for neurosurgery and ENT, the systems are classified as frameless stereotactic.

The cost of the image guided surgery system as quoted by a local company is as following (please refer appendix 1 for details).

(i) Service Package for Image Surgery System (1 year service package includes free software upgrade and 2 service visits)	RM 70,000.00
(ii) Image Guided Surgery System	RM 950,000.00

4. METHODOLOGY

An electronic search using the following databases; PUBMED, Medline via Ovid, Google as well as HTA agency databases were carried out. The following keywords were used neuronavigation system, computer assisted surgery, electromagnetic, optoelectronic, orthopedic surgery, otolaryngology, neurosurgery, either singly or in combination.The studies on use of navigation systems with a robotic arm were excluded. Only studies on using the navigation system, as image guide during surgery were critically appraised and tabulated. Cross-references were also carried out on retrieved articles

5. RESULTS & DISCUSSION

Neuronavigation had been shown to be a useful tool for planning and performing a trans-oral approach. It optimized pre-operative planning, clarifies and secures resection limits, and reduces overall surgical morbidity. Registration with an occlusal splint with four markers proved to be an attractive alternative to conventional systems (Vougioukas et al., 2003). Another study showed that this system provided precise lesion localization without limiting the line of vision, the mobility of the surgeon, or the flexibility of instruments (Zaaroor et al., 2001). The placement of electromagnetic transmitter and receiver allows flexible head positioning through the use of a headset. This system was found to be a valuable aid for the surgeon under anatomically complex conditions (Heermann et al., 2001). Neuronavigation allowed very precise intracranial and spinal surgery. The problem of brain shift during the navigation procedures was solved by intra-operative image acquisition. The use of neuronavigation was shown to improve the post-operative quality of life of patients suffering from brain and spinal tumors (Haberland et al., 2000). The data from a study suggested that the positioning of the patient's head during pre-operative imaging plays no relevant role in intra-operative accuracy of neuronavigation. However, further studies, and a larger number of patients with various pathologies in different regions of the brain are necessary to obtain a better understanding of the problem of brain shift in neuronavigation due to patient positioning alone, and to avoid procedure-related operative morbidity (Reinges et al., 2000).

5.1 Orthopedic Surgery

5.1.1 Safety

No complications influencing the clinical outcome occurred related to the use of the navigation system in hip surgery (Victor and Hoste, 2004; Perlick et al., 2004a; Perlick et al., 2004c; Hart et al., 2003; Mielke et al. 2001). There was also no particular peri- operative difficulty (Jenny and Boeri, 2001a) .

In the use of the navigation system for assisting screw placement, most studies found no post-operative neurological complications (Grutzner et al., 2004; Wendl et al., 2003; Kotani et al. 2003; Grutzner et al., 2002; Arand et al., 2001; Kamimura et al., 1999).

The most common complication found was screw penetration. Studies have shown that the perforation rate ranged from 1.2 – 4.6% and 6.7- 13.4% in the computer assisted group compared to conventional surgery (Kotani et al., 2003; Laine et al., 2000). The most common area was at the S-1 foramina, and the average length of perforation was 3 mm without impingement on the nerve root. However, this was not detected on radiographs or CT scan (Antekeier et al., 2003).

The other areas of screw perforation were at the anterior wall of the sacrum due to the navigation guide wire being bent during implantation (Arand et al., 2004). The screw perforated the pedical wall by more than 4 mm (range 1.9% to 4.6 %) in patients using the computer-assisted system (Schnake et al., 2004; Laine et al., 2000). It was also found that there were two cases that had a slight tangential screw thread penetration through the ventral sacrum (Grutzner et al., 2002). It was also observed that the maximum length of the perforation at the lateral pedicle was 2mm (Haberland et al., 2000).

Other complications noted were deep infection in the computer-assisted patients compared to the major intra-operative bleeding and post-operative death in a patient with conventional surgery (Laine et al., 2000).

5.1.2 Effectiveness

Hip Replacement

A comparative study showed that the computer-assisted navigation system used in implantation resulted in an optimal position of the acetabular component, which provided an inclination of 45±10° and an ante-version of 15±10° that could provide sufficient stability, low wear and a satisfactory range of motion in the hip joint (Stipcak et al. 2004). Another study revealed that the post-operative cup position relative to the pelvic reference plane in the navigated group had a median inclination of 45.5° and a median ante-version of 21.9° compared to the control group, where the median inclination was 41.8° and the median ante-version was 24.6°. The ninetieth percentile showed a much wider range for the control group (36.1°-51.8° inclination, 15°-33.5° ante-version) than for the navigated group (43.9°- 48.2° inclination, 18.3°-25.4° ante-version) (Nogler et al., 2004). A review found that the mean ante-version of the pelvis in conventional surgery was an average of 18° from the optimal orientation, so that there was a need to develop more reliable tools than were used or anatomically based alignment strategies to provide reproducible and accurate acetabular alignment (Digioia et al., 2002).

A study on fluoroscopy assisted freehand navigation used during the drilling of bone, found that it led to a high accuracy of three-dimensional hip placement while reducing radiation exposure to a minimum. It represents a promising and efficient application for a variety of procedures in orthopaedic surgery (Ohnsorge et al., 2003).

Total Knee Arthroplasty (TKA)

A study found that for the distal femoral cut, there was a mean varus/valgus deviation of 0.6° and a mean flexion/extension deviation of 1.4°, and for the proximal tibia, varus/valgus alignment showed a mean deviation of 0.5°. The mean sagittal variability was 1.0°. The differences between the frontal and the sagittal planes using the computer assisted technology were statistically significant (Bathis et al., 2004a). A review suggests that using an intra-operative navigation system improved the accuracy of the alignment in TKA. However, long-term studies will have to be carried out to verify whether this will lead to a lasting benefit for the patient (Oberst et al., 2003). A navigation system was said to provide significant improvement in the accuracy of implantation in TKA; and also had the advantage of precise pre-operative planning, useful documentation, and control tool for each important step (Perlick et al. 2004a, 2003).

Navigation versus conventional technique

A study found that no significant differences between the groups regarding pre-operative leg deformity (Perlick et al., 2004a, 2003).

Most studies showed a post-operative leg axis of between 3° varus and 3° valgus was achieved (Decking et al. 2005; Perlick et al. 2004a; 2004b; 2004c; 2004d; Bathis et al., 2004b; Oberst et al. 2003; Perlick et al, 2003; Jenny and Boeri, 2001b). Using navigation system produced accuracy of implantation as determined by post-operative long-leg coronal and lateral radiographs (Perlick et al., 2004a; Victor and Hoste, 2004).

Most studies found a significantly better rotation alignment and flexion angle of the femoral component in patients using a computer assisted knee navigation system than the conventional technique (Chuahan et al. 2004a, 2004b; Perlick et al., 2004d; Stockl et al, 2004; Bathis et al., 2004b; Perlick et al. 2004c, 2003; Hart et al., 2003; Sparmann et al. 2003; Jenny and Boeri 2002, 2001a). In addition, superior post-operative alignment of the mechanical axis, posterior tibial slope, and rotational alignment was achieved for patients using the computer-assisted knee navigation system (Chauhan et al., 2004a, 2004b; Stockl et al., 2004; Perlick et al., 2003; Hart et al., 2003; Sparmann et al., 2003; Jenny and Boeri 2002, 2001b).

However, one study found no difference in the analysis of the rotation position of the femoral component between the navigation and conventional groups (Oberst et al., 2003). Another study found no significant improvement in the femoral and tibial mechanical antero-posterior axis and the femoral as well as tibial sagittal tilt measured on sagittal X-rays, with computer navigation implantation (Decking et al., 2005). Another study found conflicting results, with no statistically significant difference in the parameters of a "mechanical axis", "femoral axis lat." and "tibial axis anterior posterior", whereas with regard to the parameter "tibial axis lateral", a significant difference was found in favour of the navigation system. However, the measurements of "femoral axis ap." were insignificantly better in the manual group.

Image based and non-image based

A post-operative leg axis between 3° varus and 3° valgus was obtained in both the CT-based group and in the CT-free group. However, there were no significant differences found for varus/valgus orientation (±3°) of the femoral and tibial components (Bathis et al, 2004c, 2003). Another study found that there was no significant difference in the performance of the established CT-based navigation methods from the image-guided CT free cup navigation (Grutzner et al., 2004b).

Screw Placement

Studies found that the screws were placed accurately without complications like perforation, completely contained within the osseous "safe zone" on direct dissection (Arand et al., 2004; Schnake et al., 2004; Perlick et al., 2004e; Antekeier 2003; Kotani et al., 2003; Arand et al., 2002; 2001, Grutzner et al., 2002; Laine et al., 2000; Haberland et al., 2000; Kamimura et al., 1999). However, other studies found that the screw misplacement shown in post-operative controlled CT ranged from 0.71-1.9 % (Grutzner et al, 2004a; Wendl et al., 2003; Haberland et al., 2000).

Tumour

Navigated tools oriented the surgeon to excise the tumor with adequate virtual margins during surgery, with histopathologic confirmation from analysis that the neoplasms were excised accurately within their margins (Heiland et al. 2004).

5.1.3 Cost Effectiveness

While a navigation system has significant advantages in TKA, there are additional costs and time-consuming planning, meaning that its usage is limited to special cases (Perlick et al. 2004a; Perlick et al. 2003)

5.1.4 Other aspects

Operating time

Studies found that there was longer operation time using navigation system compared to conventional techniques, ranging from 10 – 23 minute (Chauhan et al., 2004; Perlick et al., 2004a, 2004d, 2003; Grutzner et al., 2004; Jenny and Boeri, 2002; Mielke et al., 2001, Laine et al., 2000)

Exposure time

Studies showed that there was lowest average fluoroscopy time using navigation system (Perlick et al., 2004c, 2004d; Grutzner et al.. 2004a; Wendl et al., 2003)

Training

It has been recommended that application of the navigation system should be restricted to experienced surgeons who can continue the operation using a conventional approach, and who are equipped with the detailed knowledge of the principles of the tracking systems. This is necessary to prevent possible misinterpretation of information provided by the computer (Gebhard et al., 2003; Arand et al., 2002).

5.2 Neurosurgery

5.2.1 Safety

In a number of studies, it was reported that all patients recovered well without any post-operative complications (Tirakotai. et al., 2004; Hadani et al., 2001; Caversaccio et al., 1998).

However, in one study there were four patients who deteriorated post-operatively, two of which were related to intra-tumoral bleeding (Grunert et al., 2002). Another study concluded that the technique provided limited benefit in cranial nerve preservation, although no patient had permanent central neurologic morbidity as determined via post-operative MRI (Barnett et al., 1995).

5.2.2 Effectiveness

The sensitivity of the method has been reported to be 91.1%, and its specificity 82.2% (Nowacki et al. 2004). Analysis has indicated that under the guidance of a navigation system, a precise pre-surgical simulation was available in order to perform an optimal craniotomy (Schipper et al., 2004). Another study showed that the image guidance in single burr-hole procedures provided a high degree of accuracy in lesion targeting, permits good anatomical orientation and minimizes brain trauma (Tirakotai et al., 2004). It was also found that this system is able to locate the intermediate zone of brain gliomas between its central parts and the tumour edge appears to be the most appropriate neoplastic area for diagnostic stereotactic biopsy (Nowacki et al., 2004). A study also showed in that all the biopsies taken from deep-seated lesions, there was 100% histological diagnosis (Grunert et al., 2002). This system has also been shown to provide accurate planning, and resection control images during surgery were obtained with precise localization of residual tumor tissue (Hadani et al., 2001).

Another study found that with interactive surgical navigation, tumor resection was complete in all patients as determined via postoperative MRI. Thus, it was concluded that it was a useful adjunct in the operative management of some patients with intracranial meningiomas (Barnett et al. 1995).

5.2.3 Cost

A study showed the cost of using navigation system in neurosurgery remains high (Wang et al. 2002).

5.3 ENT Surgery

5.3.1 Safety

No complication was found to occur using the navigation system in assisted endoscope surgery (Qui et al., 2004; Eliashar et al, 2003; Caversaccio et al., 1999) although one patient had minor complication of a p.e-septal orbital haematoma using this system (Eliashar et al., 2003). Another study found that the problems in the use of the navigation system occurred mainly due to loss of sight of the referencing balls, and when using other surgical instruments (Khan et al., 2003)

5.3.2 Effectiveness

The image guide navigation system used in nasal endoscope procedure was able to provide accurate anatomical localization landmarks, with localization error ranging from 0.5 mm – 2.8 mm (Qiu et al., 2004; Eliashar et al. 2003; Khan et al., 2003; Grevers et al., 2002; Postec et al., 2002; Heermann et al., 2001). Another study found that the navigation system enables the precise determination of the proper site of cyst fenestration, and permits complete evacuation of a large lesion with minimal invasiveness (Nagatan et al., 2001). It has also been shown that micro-adenomas and macro-adenomas could be precisely localized by the navigation system, and could be totally removed. However, it was not useful in estimating the amount of a supra-sellar residual tumor because of the dislocation that occurred during tumor removal (Abe et al., 2001)

5.3.3 Preparatory time

The pre-operative preparatory time was found to take 10 - 20 minutes, including coordination, head-holder localization, and conventional instrument registration (Qiu et al., 2004; Eliashar et al., 2003; Postec et al., 2002; Heermann et al., 2001).

5.3.4 Cost

The navigation system was demonstrated to be a fast and simple registration method. In addition, it was also possible to use data sets obtained prior to surgery, thus, not only reducing the cost of imaging studies, but also minimizing the manpower needed to place the fiducials, and organize and perform additional acquisition of images (Grevers et al., 2002).

5.4 Surgery of Skull

Analysis has indicated that under the guidance of a navigation system, a precise pre-surgical simulation was require in order to perform an optimal reconstruction of the frontal base of skull (Schipper et al., 2004). A study also found that the measured accuracy of the system between the CT and the actual instrument location in the patient was 0.5-2 mm for the anterior skull base and 1-2.5 mm for the lateral skull base (Caversaccio et al., 1999; 1998)

6. CONCLUSION

There was sufficient evidence to support that the use of the navigation system was safe and effective in orthopedics, neurology, endoscopic nasal surgery and other ENT surgeries. However, there is evidence to show that the costs of use of this system is high, and should be restricted to experienced surgeons.

7. RECOMMENDATION

In view of the high costs, the neuronavigation system is recommended only for centers of excellence with experienced surgeon in multidiscipline, namely orthopedics, neurology and ENT surgery use so that optimal use of system is ensured.

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