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MAIN ARTICLE

Image-guided sinus surgery: practical and financial experiences from a UK centre 2001–2009

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Abstract

Background: Image guidance surgery is an emerging technology that may allow more efficient treatment of sinus disease. This retrospective study examines National Health Service and military patients who underwent procedures using image guidance surgery during the period 2001–2009.

Methods: Medical records were reviewed in terms of indications for surgery, incidence of major complications and need for revision following image guidance surgery. An attempt was also made to determine the cost-effectiveness of purchasing this navigational system.

Results: A total of 132 patients underwent 147 procedures using image guidance surgery over the 8-year period. The indications for surgery ranged from severe nasal polyposis and chronic rhinosinusitis to malignant tumours in the paranasal sinus and skull base region. Average length of follow up was 17.6 months. Four patients had a major complication. Fourteen patients underwent revision surgery. The cost of providing an image guidance surgery service was estimated to be £110,000–120,000 during the study period. The economic model for the subgroup of nineteen military patients (with non-polypoid chronic rhinosinusitis) suggests that use of this technology will reduce overall costs by approximately £70,000 when compared with conventional sinus surgery.

Conclusion: This study provides some evidence that image-guided sinus surgery is cost effective, safe and may decrease surgical revision rates.

Key words: Paranasal Sinuses; Computer-Aided Surgery; Endoscopy

Introduction

Functional endoscopic sinus surgery (FESS) is one of the most commonly performed procedures in otolaryngology, and the treatment of choice for various forms of sinonasal pathology.

Within the past 20 years, the combined literature reporting on the indications, methods and efficacy of this technique suggests that treatment with FESS has resulted in more complex disease processes. There remains a definite risk of complications associated with FESS. These include major bleeding, orbital damage and cerebrospinal fluid (CSF) leak. These risks are exacerbated in revision surgery in which the usual anatomy may be distorted or absent.

Image guidance surgery is a new and evolving technology. It provides the surgeon with a three-dimensional visual representation of a patient's anatomy and the relative position of surgical instruments.

Image guidance systems use either an infrared camera or a radiofrequency signal to track the location of a surgical instrument relative to the patient's head. A computer workstation processes this data, which can be used to confirm the anatomical location of the instrument within the sinus cavities, as well its proximity to the adjacent skull base and orbit (Figure 1).

This theoretically results in a lower incidence of perioperative complications and may improve the outcome of surgery. However, many reports describe small cohorts of patients undergoing this procedure, with limited follow up. The long-term safety and efficacy of image guidance surgery has not been adequately established. We present our eight-year experience with image guidance surgery in a cohort of military and civilian patients from a UK centre.

Materials and methods

This is a retrospective study of all patients who underwent image guidance surgery at the Royal Hospital Haslar and Queen Alexandra Hospital (Portsmouth) between the years 2001–2009. In this period, 132 patients underwent image guidance surgery. One patient was lost to follow up and was not included in this study. The medical records of the remaining

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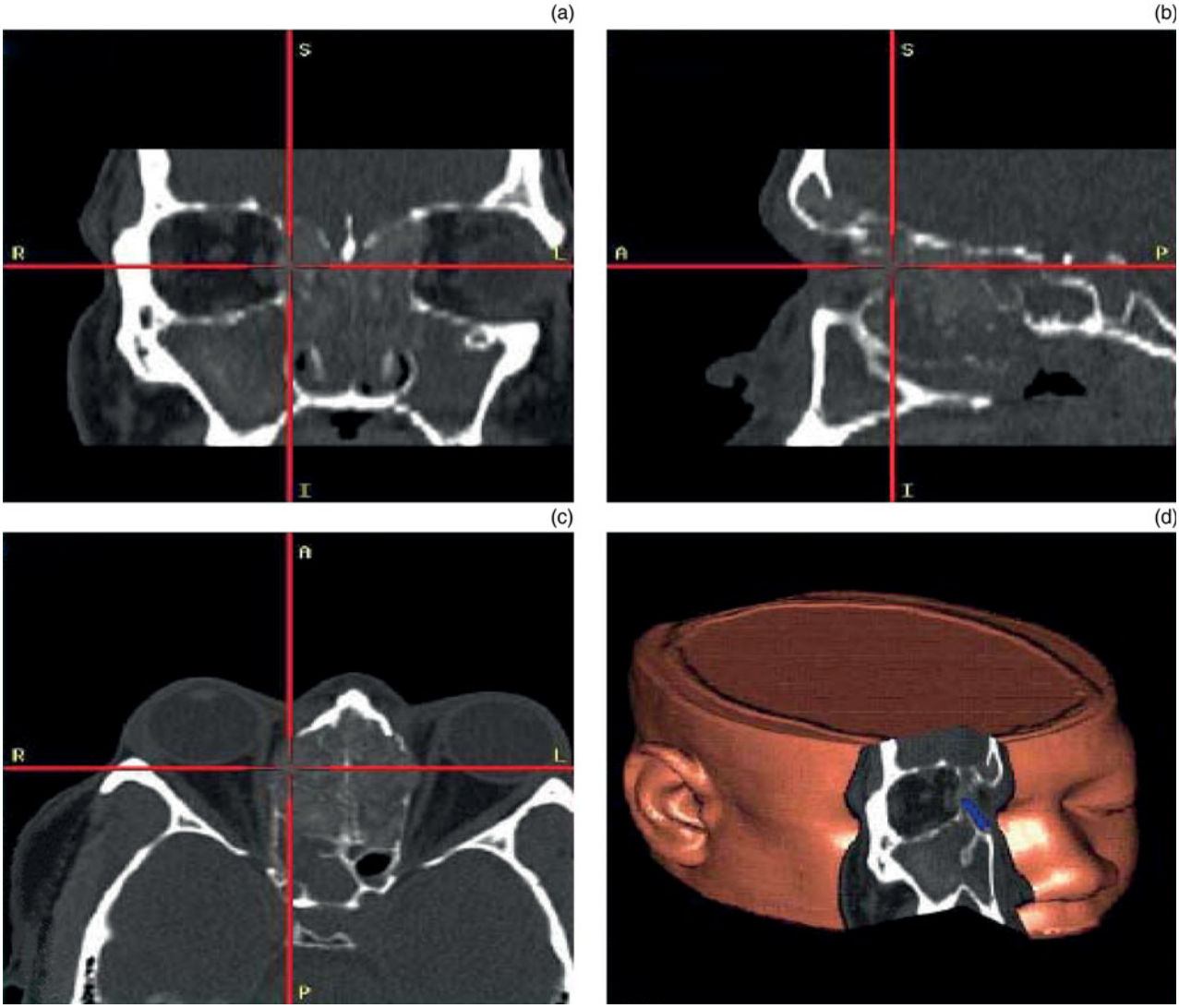

FIG. 1

Pre-operative computed tomography images as used in image-guided surgery, including (a) coronal, (b) sagittal, (c) axial and (d) 3-D views showing a right anterior ethmoid sinus mucocele with demineralisation of the medial orbital wall. The crosshairs show the location of the tip of the surgical instrument. S = superior; R = right; L = left; I = inferior; A = anterior; P = posterior

131 patients were reviewed and judged to be appropriate for inclusion in the study.

The demographic data collected included age at time of surgery, gender, prior surgical interventions, indication for image guidance surgery and length of follow up. Records were also reviewed for the incidence of major complications and the need for revision surgery. A major complication was defined as the occurrence of any one of the following events: orbital trauma; optic nerve injury; intra-operative injury to a major blood vessel with bleeding (more than 250 ml); CSF leak; trauma to intracranial structures; and post-operative epistaxis requiring blood transfusion, placement of intranasal packs, surgical ligation, or embolisation.[1]

The LandmarX optical system (Medtronic, Jacksonville, Florida, USA) was used for all image-guided surgery.[2,3] The pre-operative radiology protocol utilised a 2-mm thickness axial computed tomography (CT) scan of the paranasal sinus region. This dataset was transferred via compact disk read-only memory to the operating theatre workstation, and the images were loaded onto the image guidance surgery system prior to the procedure to check for quality and accuracy.

As we used an optical-based system, the overhead infrared emitting device would not allow any line-of-sight obstruction to the patient and/or surgical instruments (which in practice was not found to be a significant problem). Registration generated a correlation between the position of the instrument in the surgical field and the corresponding location on the CT scan. The instruments were registered to show their position with respect to the three-dimensional CT images of the patient using four anatomic fiducials (lateral and medial orbital edge, columella, and nasion). The location was confirmed by crosshairs on the screen that moved through the CT image data in concordance with the movement of the pointer.

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TABLE I
OPERATIVE CHARACTERISTICS

Characteristic	Value
Pts (*n*)	132
IGS procs (*n*)	147
Age (y (range))	46 (3–84)
Male (%)	68.9
Smoker (%)	14.4
Samter's triad (%)	12.1
Mean FU (mth (range))	17.6 (3–72)
Mean prev procs (*n* (range))	1.52 (0–26)
Rev surg (%)	59.1
Frontal sinus surg (%)	53.5
Sphenoid sinus surg (%)	33
Intra-op re-reg (*n*)	1

Pts = patients; IGS = image guidance surgery; procs = procedures; y = years; FU = follow up; mth = months; prev = previous; rev = revision; surg = surgery; intra-op re-reg = intra-operative re-registration

Results

Between 2001 and 2009, 132 patients underwent 147 image guidance surgery procedures (Table I). There were 91 men and 41 women in the study. Age at the time of surgery ranged from 3 to 84 years, with a mean age of 46 years. The average length of follow up was 17.6 months (range 3–72). The indications for surgery ranged from severe nasal polyposis and chronic rhinosinusitis to malignant tumour in the paranasal sinus and skull base region (Table II).

A review of the records of all patients revealed a statistical mean of 1.52 procedures (range 0–26) per patient before image guidance surgery. There were four major complications (3.0 per cent). Intra-operative re-registration was required in one case where the navigation probe was located 5 mm off target. Two patients underwent CSF leak closure using image guidance surgery as a result of an intra-operative complication.

A revision procedure was required in 14 patients who had undergone initial image guidance surgery. Ten of these patients required a revision procedure for nasal polyposis, two for mucocele, one for chronic sinusitis and one for neoplasia. The principal cause for revision was persistent infection and/or poor ventilation of a sinus cavity. Excessive bleeding was responsible for the early termination of three procedures necessitating repeat surgery at a later stage. A lack of hypotensive anaesthesia was noted for two of these three cases. A Lothrop procedure (the artificial creation of a common frontal sinus cavity) was required for one refractory barotrauma patient and in one interesting case where the left frontal sinus connected with the right side of the nose.

TABLE II
INDICATIONS FOR IMAGE GUIDED-SURGERY

Diagnosis	Proc 1	Proc 2	Mult proc	Total
CRS	6	6	7	19
Nasal polyps	29	14	48	91
Barotrauma	9	2	0	12
Mucocele	2	3	4	9
Orbital	3	0	1	4
Neoplasia	5	4	0	9
CSF otorrhoea	0	1	1	2
Atresia	1	0	0	1

Data represent numbers of patients. Proc 1 = first procedure; proc 2 = second procedure; mult proc = multiple procedures (more than two); CRS = chronic rhinosinusitis; CSF = cerebrospinal fluid

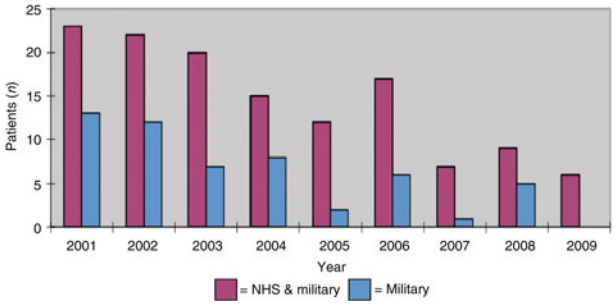

FIG. 2
Number of patients who underwent image guidance surgery (2001–2009). NHS = National Health Service

Figure 2 illustrates the frequency trend of image guidance surgery for all National Health Service (NHS) and military patients. Initially, there were a large number of patients undergoing image guidance surgery, which may reflect the enthusiasm for this technique. However, after a few years the number of new patient procedures decreased, which may indicate a refinement in selection criteria.

Figure 3 shows the average image guidance surgery procedure time (from registration to de-scrubbing) for all cases, and the time taken for the most popular procedure (bilateral frontal FESS) performed by the surgeon with the most cases. The figure indicates that the time taken to perform the more specific procedure (FESS) decreased over the years. This could be due to a reduction both in registration time and the number of intra-operative setbacks with image guidance surgery.

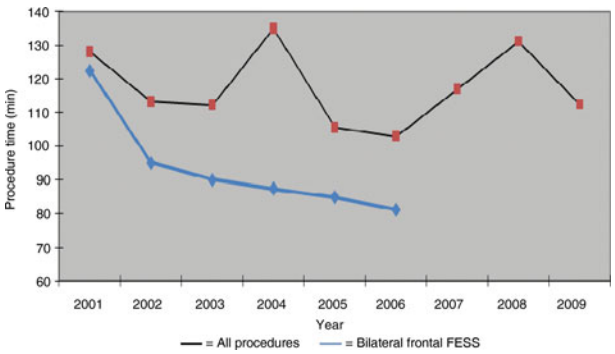

FIG. 3
Average procedure time for image guidance surgery (for National Health Service and military patients combined). Min = minutes; FESS = functional endoscopic sinus surgery

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TABLE III
FACILITY CHARGE FOR IMAGE-GUIDED SURGERY

Provision	Cost* (2001–2004)	Cost* (2005–2009)
OT time	150†	0‡
Maintenance	105	215
Radiology	20	20
Sterilisation	20	20
Disposables**	0	0
Total	295	255

*Cost per patient (£). †Delay of more than 15 minutes. ‡Delay of less than 15 minutes. **No disposable items required for optical system registration. OT = operating theatre

To describe the financial aspects, it is important to differentiate between cost and charge. Cost in this context includes the expense incurred with the acquisition of this technology.[2] The initial purchase cost of the system in 2001 was £75,000 with a further £5000 added for software installation. Charge reflects a facility fee for the ongoing provision of the navigational system and is reported to include the cost of maintenance, specialist radiological input, increase in operating theatre time, consumable items and sterilisation costs.[4] This information was used to calculate a local fee of £255 per patient for the period 2005–2009 (Table III). The facility charge was noted to be higher for the period 2001–2004 as a result of longer intra-operative delays. Due to the turnaround time taken to sterilise the equipment, it was not possible to carry out more than two navigational procedures in a single 24-hour period.

A cost analysis based on aircrew patients with non-polypoid chronic rhinosinusitis before and after the introduction of image guidance surgery indicated an overall saving to the military (Table IV). It was not possible to collect such information for NHS patients.

TABLE IV
COST ANALYSIS*

Cost to military	Conventional surg	IGS
Pts (*n*)	19	19
Operations (*n*)	32	21
Male (%)	88	82
Age (y)	37	41
Rev surg (%)	68	11
Frontal sinus surg (%)	69	78
Major complication†	1	1
Primary proc‡ (£)	114,000	114,000
Secondary proc‡ (£)	78,000	12,000
IGS attributable cost** (£)	–	11,500
IGS attributable charge§ (£)	–	6,300
OT session charge (£)	64,000	42,000
Total (£)	256,000	185,000

*For non-polyposis military patients. †Major epistaxis (conventional) or cerebrospinal fluid leak (IGS). ‡Sick leave, approximately £6000 for each operation. **Purchase fee divided by number of patients. §Calculated as £300 per patient. Surg = surgery; IGS = image guidance surgery; pts = patients; y = years (median); rev = revision; proc = procedure; OT = operating theatre

Case report

An example of the utility of the system is provided by the case of a 32-year-old male soldier who presented with increasing mid-facial pain and mild blurring of vision. The CT examination showed mild proptosis and a mucocele in the right ethmoid sinus, with evidence of destruction of the lamina papyracea (Figure 1). The goal of the operation was to decompress and marsupialise the mucocele using an endoscopic approach. By employing image guidance surgery, it was possible for the surgeon to fully delineate the lateral limit of dissection, and carry out the procedure without damage to the medial rectus muscle or the anterior and/or posterior ethmoid artery. The patient went on to have an uncomplicated recovery, with no visual deficit in the post-operative period.

Discussion

With more than 14,000 cases performed annually in the UK, FESS is one of the more frequently performed procedures in otolaryngology.[5] It is associated with both intra-operative and post-operative complications including major arterial bleeding, orbital damage, dural tear resulting in CSF leak, intracranial injury and death.[1] The potential complications are more concerning when advanced disease processes distort the normal anatomy. Post-operative changes may also lead to the loss of surgical landmarks and the shift of important structures.[6]

Accuracy

Surgical navigation systems were first brought into significance in neurosurgery and otolaryngology in the 1980s.[7] Multiple studies have reported on the accuracy of image guidance surgery.[8–11] A review of multiple different navigational systems by Metson *et al.* showed an overall accuracy of within 1–2 mm.[10] Theoretically, this improved anatomical accuracy should decrease morbidity and improve the efficacy of the procedure. If anatomical drift of more than 2 mm occurs, the registration process should be re-started. Above all, the surgeon should always place clinical instinct above image guidance surgery if conflict exists.[10,11]

Complications

The increased popularity of navigational systems over the past 15 years has enabled sinus surgery to be carried out on more challenging cases. However, long-term analysis of the safety and efficacy of image guidance surgery remains limited. Loehrl *et al.* reviewed 31 patients who underwent image guidance surgery for frontal sinus ventilation and found no complications, however, revision endoscopic or open procedures were required for six patients (20 per cent), the majority of whom had aspirin triad disease.[12] In a separate review, Reardon *et al.* showed a small difference in major complication rates that favoured image

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guidance surgery over traditional surgery, but this did not achieve statistical significance.[13] Multiple retrospective studies from various centres have also reported lower complication rates using image guidance surgery,[10,11] however, only one paper found significant differences.[14]

This paper reports on our experience with image guidance surgery in a cohort of 132 patients, with a mean follow up of 1.5 years. The complication rate in this series (3.0 per cent) suggests that navigational assistance can help to reduce the risks associated with complex or revision surgery. In view of the absence of a control group in this study, a comparison of our results to prior reviews of complications associated with revision and primary sinus surgery indicates improved safety with navigational assistance. One observational study reviewed 142 patients who underwent FESS without navigational assistance and revealed an increased incidence of major complications (9.9 per cent) associated with revision surgery.[15] A number of studies investigating primary FESS have shown complication rates of between 0.3–3.0 per cent.[1,16]

Many clinicians would support the use of an image-guidance system for safer and more thorough surgery. As mentioned above, this benefit has yet to be unequivocally demonstrated. Major complications resulting from sinus surgery are relatively rare. Therefore, several thousand cases would need to be monitored prospectively to demonstrate the impact of this technology on complication rate.[1,7] Furthermore, because image-guidance systems may instil a false sense of security when first used, the complication rate could actually increase initially as this new technology becomes more widely available. We note the one complication of a CSF leak in our series occurred in the first year of using IGS.

Efficacy of surgery

Despite the potential for improved surgical clearance of disease, the requirement for revision surgery after image guidance surgery remains a persistent problem. In our series of 132 patients, 14 patients (10.6 per cent) required revision surgery. The majority of these patients had surgery for nasal polyposis (an incurable disease), with subsequent disease recurrence causing persistent infection and/or poor sinus ventilation. Three patients had initial incomplete surgery due to excessive bleeding or equipment failure. The cause of recurrent infection after surgery is often multifactorial, with contributing factors including the extent of sinus disease, anatomic abnormalities, systemic disease, inadequate surgical intervention and variable medical management.

In this series, the majority of patients who received image guidance surgery had undergone previous sinus operations (60 per cent), reflecting a selective sample of refractory patients. Our results are similar to the failure rates following primary FESS (2–24 per cent), and significantly better than the failure rates following revision surgery.[16,17] A review by King *et al.* of the clinical demographics of 43 patients who underwent non-image guided revision FESS revealed a 69.8 per cent success rate after a mean follow up of 14.1 months. The following were noted as predisposing factors in unsuccessful revision: compromised immune status, asthma, oral steroid use, allergic fungal sinusitis and polyps.[17] Jiang *et al.* reported a 65 per cent improvement rate after non-image guided revision FESS, which was similar to the previous study.[16] In contrast, Loehrl *et al.* reported an 80 per cent success rate of frontal sinus ventilation in 31 cases of frontal sinus image guidance surgery.[11] These findings, in conjunction with the 90 per cent success rate in our series, suggest that image guidance may improve efficacy in the treatment of complex sinus disease.

Changing indications

The reduction in the utilisation of the image guidance facility over the study period may reflect a more selective criterion for surgery. It can also be argued that image guidance surgery is not for every clinician. This technology can distract the surgeon, interrupt the operating theatre routine and is a relatively complex technique. Unless the surgeon is willing to accept a frequent number of initial setbacks, the use of an image guidance system can prove frustrating. If normal anatomical landmarks are present and the patient's disease is limited to the ethmoid or maxillary sinuses, an image guidance system does not usually enhance the procedure. Even in cases where sphenoid or frontal sinus disease is present, the surgeon may feel more comfortable with the use of conventional instrumentation to identify the obstructed sinus ostium.

Cost effectiveness

Image guidance systems are currently available for between £40,000 - £100,000.[3] The majority of manufacturers will consider lend-lease contracts, which are accompanied by regular maintenance services and technology updates. In the NHS, this reduction in initial costs will enhance a business case to health commissioners.

In the literature, the additional charge of navigational surgery is thought to be incurred primarily as a result of delayed operating theatre set-up time.[2,4,7,14,17] The observations made by the current study suggest that image guidance surgery operative set-up time becomes negligible (less than 5 minutes) after an adaptive period, and hence may be reduced considerably. This view is supported by research from both Metson and Stelter *et al.*[10,11] The largest facility charge identified was the annual maintenance fee. The exact figure will vary according to the volume of surgical procedures undertaken by individual units.[3]

British military records reveal that aircrew undergoing conventional sinus surgery for non-polypoid chronic rhinosinusitis had an average of two procedures

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before returning to full fitness. As demonstrated in Table IV, the recurrence rate with image guidance surgery in the current series was approximately 10 per cent. For the cohort of 19 patients undergoing image guidance surgery, the attributable cost to the Ministry of Defence was £18,000, with a net saving of approximately £70,000. This saving was mainly based on a swifter return to full duties and a decrease in the requirement for revision surgery.

- **An increasing number of patients are receiving image-guided sinus surgery**
- **This study assessed the safety, efficacy and financial aspects of navigational sinus surgery**
- **It was noted that utilisation of this technology decreased over the study period**
- **Image guidance surgery may be useful for complex or revision sinus surgery in select patients**
- **Financial remuneration within the NHS may need to change in order to facilitate this technology**

Thus, although navigational technology is seen as an expensive asset, the business case is enhanced by considering the overall economic picture. Such a situation is recognised in the USA by the provision of a separate procedure code for navigational technology, which offers increased remuneration.[4]

Limitations

The limitations of this study include its retrospective, non-randomised design and the lack of an adequate control group. In addition, it is difficult to compare this new technology with conventional methods (in terms of how safe it is or how long it takes) due to the multiple factors involved, such as the case mix or operative experience of the individual surgeon.

Conclusion

Image guidance surgery appears to increase safety and efficacy in revision and complex primary cases. However, the number of surgical procedures performed in the current series decreased over time. In our 8-year review of 147 cases, there were 4 major complications with a 90 per cent overall success rate.

Image guidance surgery is the most significant advance in sinus surgery since the inception of the endoscopic approach in the mid-1980s. Image guidance systems enable the surgeon to follow the anatomical dissection of the sinuses on a computer monitor in the operating theatre. Important anatomical relationships can be more easily understood and treated with the assurance that the critical landmarks are secured.

Early acquisition of this technology was achieved with direct funding from the Ministry of Defence. Analysis of the economic model for military aircrew patients suggests that the initial expense and running costs can be recovered within the time frame of this study.

At present, with current funding arrangements, one must conclude that image guidance surgery is unlikely to be cost-effective for individual NHS units. However, consideration of loss to the wider UK economy associated with decreased productivity may provide the basis for change. If a sufficient increase in funding for this technology is provided through payment by results, this may enable other hospitals to purchase or hire image guidance surgery systems. The other challenge is for companies marketing this technology to produce systems within financial reach of otolaryngology departments in an era in which control of costs is a high priority.

Image guidance is not a substitute for thorough surgical training, knowledge of surgical anatomy or sound intra-operative surgical decision making. However, improvements in technology may lead to better accuracy, reliability and utility, and image guidance surgery may emerge as an indispensable component of advanced sinus surgical techniques.

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