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Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon scanning technology prioritising summary

StatScan critical imaging system

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**Australian
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and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



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College of Surgeons**

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PRIORITISING SUMMARY

NAME OF TECHNOLOGY **LODOX STATSCAN CRITICAL IMAGING SYSTEM (REFERRAL)**

PURPOSE AND TARGET GROUP **PROVIDE RAPID (13 SECONDS) WHOLE-BODY, SKELETAL AND SOFT-TISSUE, LOW-DOSE X-RAY TO TRAUMA PATIENTS**

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|--|
| <input checked="" type="checkbox"/> Yet to emerge
<input type="checkbox"/> Experimental
<input type="checkbox"/> Investigational
<input type="checkbox"/> Nearly established | <input type="checkbox"/> Established
<input type="checkbox"/> Established <i>but</i> changed indication or modification of technique
<input type="checkbox"/> Should be taken out of use |
|---|--|

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|---|-----------------------|
| <input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No
<input type="checkbox"/> Not applicable | ARTG number NA |
|---|-----------------------|

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
South Africa			✓
United States*		✓	
Sudan*		✓	
Switzerland	✓		

*8 machines in the United States and 2 machines in Sudan (Knobel et al 2006).

IMPACT SUMMARY

StatScan provides trauma doctors with critical information about a patient’s injuries so that necessary treatment can be determined, potentially improving patient outcomes by reducing the time between admission and access to treatment.

BACKGROUND

StatScan is a digital x-ray scanning system that can produce diagnostic, full-body x-ray images in 13 seconds. StatScan appears to be particularly useful in trauma and emergency patients because the patient can be easily accessed with minimal manoeuvre required, and the full-body images it provides are capable of detecting multiple injuries, which are

often missed by conventional sized x-rays. In emergency medicine, the time period following a traumatic injury being sustained during which there is the highest likelihood that prompt medical treatment will prevent death is referred to as the ‘golden hour’, and may actually last from a few minutes to several hours. The rapid acquisition of diagnostic images achievable using StatScan allows trauma patients rapid access to specialised treatment and in turn should improve their treatment and survival outcomes.

StatScan has a rotating anode x-ray tube mounted on one end of a C-arm which emits a low-dose, collimated fan-beam of x-rays (Pitcher et al 2009). Fixed to the other end of the C-arm is the x-ray detector unit (Evangelopoulos et al 2009) (Figure 1). The C-arm can travel the length of the table at up to 138 mm per second (Evangelopoulos et al 2009). StatScan captures anteroposterior images; however, whole-body, horizontal beam, shoot-through lateral, erect, and oblique views may also be taken (Evangelopoulos et al 2009). The StatScan unit also includes an integrated docking resuscitation table to eliminate transfer of the patient and allow complete patient access for resuscitation (Evangelopoulos et al 2009). The images are immediately available via a personal computer and may be enlarged for better viewing (Evangelopoulos et al 2009).

Figure 1: StatScan in the anteroposterior imaging position.



(Image taken from www.Lodox.com)

Other uses for StatScan include forensic applications (such as locating bullets or foreign bodies), bone cancer detection, urinary stone detection, and diagnosis of acute ventriculoperitoneal shunt dysfunction. In particular, diagnosis of acute ventriculoperitoneal shunt dysfunction traditionally requires serial two-dimensional conventional radiographs of the skull and chest (and possibly the abdomen) and because shunt malfunction may be a common complication, repeated radiation exposure may lead to an increased risk of malignancies (Evangelopoulos et al 2009). StatScan purportedly minimises this risk by achieving adequate imaging using a single, low-dose scan. The majority of studies identified used StatScan in trauma patients, for this reason, this summary focuses on this indication alone.

CLINICAL NEED AND BURDEN OF DISEASE

Comprehensive clinical and radiological evaluation of multiply injured patients is challenging, consequently diagnostic error rates have been documented between 2.5% and 20% (Pitcher et al 2009). Errors are primarily due to inadequate radiographic practise, with missed fractures constituting the largest proportion (Pitcher et al 2009).

Imaging of a polytrauma patient is not only time consuming and technically difficult, each radiographic exposure increases the dose of ionizing radiation the patient is exposed to. The risk of cancer is increased with the radiation dose of each examination, and in the tissues of children in particular, cellular infrastructure may be modified and predispose them to malignant change later in life (Pitcher et al 2009). StatScan is a potential low-dose alternative to existing devices, therefore decreasing the risk associated with diagnostic imaging in trauma patients.

The Australian Institute of Health and Welfare (AIHW) reported 2% of cancers were due to radiation exposure (AIHW 2010).

DIFFUSION

ScatScan was developed by De Beers in South Africa for use in the diamond-mining industry for theft surveillance, so that full-body scans could be taken of workers in order to detect diamonds that may have been hidden in clothing or swallowed, at this time the unit was known as Scannex (Knobel et al 2006). The motivation for its development was the need for an imaging technique that used the lowest possible radiation level to provide a good quality image, which was safe enough for daily use. In 1995, StatScan was recognised for its diagnostic potential and subsequent research found it to provide similar quality images to that of conventional radiographs, culminating in the United States Food and Drug Administration (2002) and the European Union (2004) approving the unit for radiographic examination of both trauma and standard emergency patients (Pitcher et al 2009). About 25 trauma centres worldwide have incorporated StatScan into their emergency management protocols (Evangelopoulos et al 2009).

StatScan is yet to emerge in Australia and consequently did not exist on the Australian Register of Therapeutic Goods at the time of writing. Correspondence with the Australian and New Zealand distributor of StatScan (ATX Medical Solutions) revealed they are currently working with two hospitals in Australia in regards to the installation of a StatScan unit; however, no units were in operation at these sites as yet.

COMPARATORS

The current gold standard in emergency department's trauma imaging is CT scanning. It is important to note that StatScan is not a CT scanner; therefore, should not be considered a replacement. It is more likely that a combination of StatScan imaging, focused abdominal sonography for trauma, and a thorough clinical examination may reduce the number of CT scans taking place in an emergency setting.

The 7th edition of the ATLS Guidelines (2004) recommends three x-rays as part of the primary patient survey (cervical spine, thorax, and pelvis) (Deyle et al 2009). These images are obtained by bedside machines so they can only be acquired in one plane and

are therefore limited (Deyle et al 2009). Delays due to the positioning of the portable x-ray system, high direct and scattering radiation, and practical difficulties in acquiring satisfactory images can adversely affect patient management, morbidity, and mortality (Deyle et al 2009). Conventional x-rays can also be considered a comparator for whole-body, low-dose x-ray StatScan.

SAFETY AND EFFECTIVENESS ISSUES

A total of four comparative studies were identified for inclusion in this summary (Deyle et al 2010; Deyle et al 2009; Exadaktylos et al 2008; Beningfield et al 1999). All of these studies looked at the use of StatScan in trauma patients and compared its diagnostic efficacy with that of conventional imaging techniques. The two studies by Deyle et al (2009 and 2010) report outcomes in the same patient population and are therefore reported as a single study below.

In the studies by Deyle et al a retrospective chart analysis of a total of 245 consecutive polytrauma patients, aged 16 years or older, was undertaken. Each patient underwent StatScan imaging followed by full-body CT scanning. Where possible, the following diagnoses were compared between StatScan and CT images, chest injuries with pneumothorax, signs of lung contusion, mediastinal injuries (rupture of the aorta or pneumomediastinum), thoracic skeletal lesions (fractures of the ribs and clavicles), or peripheral bone fractures. Of the 245 patients, 172 were men and 73 women. The most common causes of injury were motor vehicle crash (60%), falls from height (20%), and pedestrians hit by motor vehicles (10%). Mean Injury Severity Score (ISS)¹ was 20 (range: 16-86²).

Exadaktylos et al (2008) reported the use of StatScan in 143 consecutive trauma patients between October 2006 and February 2007 and compared their outcomes with those of 650 patients treated between January 2002 and January 2004 with conventional ATLS protocol (conventional x-ray). Mean ISS in the treatment group was 15 ± 14 (range: 3-75) and mean ISS in the control group was 14 ± 14 (range: 3-75).

The study by Beningfield et al (1999) describes an initial experience of using the low-dose, full-body x-ray security system (Scannex) for diagnostic purposes before the unit was redesigned and marketed for medical use as StatScan. Detailed image quality testing and radiation dose measurement using standard medical physics equipment and techniques were undertaken. A total of 65 trauma, medical and paediatric patients were evaluated; 32.3% (21/65) of patients had gunshot wounds, 21.5% (14/65) had stab wounds, 20% (13/65) were involved in a motor vehicle accident, 4.6% (3/65) suffered a fall, 3.1% (2/65) had a blunt injury, and 18.5% (12/65) had another condition. The mean age of the patients was 36 years (range: 0-86 years).

¹ Injury Severity Score takes values from 0 to 75. The Injury Severity Score is the only anatomical scoring system in use and correlates linearly with mortality, morbidity, hospital stay and other measures of severity (Baker et al 1974).

² It is unclear why the ISS upper range is greater than 75 in this case.

Safety and Effectiveness

Deyle et al (2009) reported the efficacy of detecting chest, thoracolumbar spine and pelvis injuries using CT scan and StatScan images. Table 1 below summaries the results obtained.

Table 1: Chest, thoracolumbar spine and pelvis injuries detected by CT versus StatScan.

Injury	Number of patients (%)		Sensitivity
	CT scan	StatScan	
<i>Chest</i>			
Pneumothorax	54/245 (22%)*	26/49 (54%)	54%
Lung contusion	60/245 (24%)	27/60 (45%)	45%
Mediastinal injuries	13/245 (5%)	7/13 (54%)	54%
Fractured ribs and clavicles	85/245 (35%)	62/85 (73%)	73%
Multiple rib fractures	50/245 (20%)	43/50 (86%)	86%
<i>Thoracolumbar spine</i>			
Thoracic spine fractures	44/245 (18%)	19/44 (43%)	43%
Vertebral body and spinous fractures	35/245 (14%)	18/35 (51%)	51%
Lumbar spine lesions	54/245 (22%)	40/54 (74%)	74%
<i>Pelvis</i>			
Pelvic injuries	41/245 (17%)	28/245 (11%)	11%
Stable injuries	16/41 (39%)	9/16 (56%)	56%
Pelvic fractures	17/41 (41%)	12/17 (71%)	71%
Rotationally and vertically unstable lesions	8/41 (20%)	7/8 (88%)	88%

*Five patients excluded because tubes in situ.

Additional sensitivity and specificity results reported in the later study by Deyle et al (2010) for peripheral bone injuries are presented below in Table 2.

Table 2: Sensitivity and specificity of StatScan in detecting peripheral bone injuries.

	Sensitivity	Specificity
<i>Limbs (excluding hands and feet)</i>		
Shoulder lesions	72%	100%
Distal humerus fractures	90%	100%
Forearm fractures	64%	100%
Femoral fractures	88%	100%
Tibia/fibia fractures	80%	100%
<i>Hand and feet</i>		
Hand fractures	55%	100%
Foot fractures	45%	100%
Overall excluding hands and feet	81%	100%
Overall including hands and feet	73%	100%

The results reported in the studies by Deyle et al (2009 and 2010) indicate the sensitivity of StatScan to be 45-86% for detecting chest injuries, 43-74% for detecting

thoracolumbar spine injuries, 11-88% for detecting pelvis injuries, 64-90% for detecting limb injuries (excluding hands and feet), and 55% and 45% for detecting hand and foot injuries, respectively. Based on these results, StatScan does not appear to be as effective as CT scanning in detecting several types of injuries.

Exadaktylos et al (2008) reported a total-body scanning time of 3.5 minutes (range: 3-6 minutes) for StatScan compared with 25.7 minutes (range: 8-48 minutes) for conventional x-rays. The total emergency room time for both groups of patients (those undergoing StatScan images and those undergoing conventional plain radiography) was similar (28.7 minutes; range: 13-58 minutes versus 29.1 minutes; 15-65 minutes). Of the 143 patients undergoing StatScan images, 81% (116/143) required additional CT scans, and in 84% (98/116) of these, full body trauma CT scans were necessary. Fifteen percent (18/116) of patients required selective CT scans based on StatScan findings and 30% (43/143) of patients had additional x-rays performed, mainly due to inadequate anteroposterior views of fractured bones.

Finally, the study by Beningfield et al (1999) measured radiation dose in addition to assessing image quality. Overall radiation dose was very low, both in the direct beam and from scattered radiation. The mean entrance surface dose to the patient was 6.2 micro-Sieverts, which was approximately 3% (range: 0.3-13%) of the conventional radiation dose. The same reduction in radiation dose (3%) was noted for staff standing adjacent to the modified Scannex unit compared with conventional x-ray machines.

On a case-by-case basis, in regards to image quality, modified Scannex performed as well as conventional radiography in 40.6% (26/64) of cases, and in one case (1.6%) modified Scannex was superior to conventional radiography. Digital performance was equal to that of conventional radiographs in 42.9% (67/156) of specific pathological features, and in 12.8% (20/156) it provided additional information compared with conventional radiographs. Table 3 below describes this in greater detail.

Table 3: Specific radiographic features detected by modified Scannex versus conventional x-ray.

Specific feature	Conventional x-ray	Modified Scannex	Sensitivity
Patients	64	26	40.6%
Fractures	41	13	31.7%
Rib fractures	13	5	38.5%
Skull fractures	2	0	0%
Pneumothorax	18	11	61.1%
Haemothorax	7	7	100%
Pneumomediastinum	3	2	66.7%
Surgical emphysema	16	11	68.8%
Extraluminal air	2	1	50%
Opacification	24	13	54.2%
Bullae	6	0	0%
Other	55	18	32.7%
Total	156	67	42.9%

None of the included studies reported complications that occurred in association with the StatScan imaging procedure (Deyle et al 2009; Deyle et al 2010; Exadaktylos et al 2008; Beningfield et al 1999).

COST IMPACT

The acquisition costs of StatScan are similar to those for conventional hospital imaging products (Evangelopoulos et al 2009). Material and running costs appear to be low because the device operates with compatible digital computerised software using conventional computer hardware. One study reported no additional costs in regards to staff time or service costs (Evangelopoulos et al 2009).

ATX Medical Solutions provided a budgetary price for a StatScan system, at \$550,000 excluding GST.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There were no issues identified from the retrieved material.

OTHER ISSUES

One study reported that both radiographic and medical staff found modified Scannex easy to use after approximately 30 minutes of tuition. Image retrieval and manipulation through personal computer software was subjectively rated as satisfactory by the users, although the user interface was felt to require simplification (Beningfield et al 1999). It is likely during the redesign of the unit the user interface has been updated.

SUMMARY OF FINDINGS

From the literature StatScan appears to offer an improvement in time management when treating trauma patients and effectively reduces radiation exposure to patients and their carers. However, at this stage, StatScan appears to be less sensitive in detecting injuries in trauma and emergency patients compared with conventional radiographic techniques (including CT scanning and x-ray imaging) in many cases; therefore, based on these findings StatScan may be suitable for use adjunct to conventional imaging and examination, instead of as a single diagnostic modality.

HEALTHPACT ASSESSMENT

StatScan appears to have the potential for rapid diagnosis of traumatic injuries, however the technology requires further refinement and development before it can be utilised effectively within a clinical setting. HealthPACT has noted this technology but no further assessment by HealthPACT is necessary at this time.

NUMBER OF STUDIES INCLUDED

Total number of studies	4
Level III-2 evidence	2
Level III-3 evidence	2

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

StatScan OR Lodox StatScan

Low-dose AND digital xray

Critical imaging system

HEALTH PACT DECISION

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

PRIORITY RATING

- High** **Medium** **Low**