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Horizon Scanning Technology Prioritising Summary

T-Stat system for the detection of tissue ischemia

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PRIORITISING SUMMARY

REGISTER ID: 000418 (REFERAL)
NAME OF TECHNOLOGY: T-STAT ISCHAEMIA DETECTION SYSTEM
PURPOSE AND TARGET GROUP: FOR THE ASSESSMENT OF OXYGEN IN TISSUES IN POTENTIALLY ISCHAEMIC IN PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

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

INTERNATIONAL UTILISATION:

| COUNTRY | LEVEL OF USE | | |
|---------|------------------------------|-------------|-----------------|
| | Trials Underway or Completed | Limited Use | Widely Diffused |
| USA | | ✓ | |
| UK | ✓ | | |

IMPACT SUMMARY:

Spectros Corporation manufactures the T-Stat[®] ischaemia detection system for the assessment of oxygen levels in tissues. The device would be used during various procedures which require accurate measurement of tissue oxygen levels, such as vascular or gastro-intestinal surgery. The T-Stat would be mainly used in hospital or other surgical clinics.

BACKGROUND

Ischaemia is the inadequate supply of blood to a tissue, resulting in damage to the tissue due to a lack of oxygen and the subsequent built up of metabolic waste. Reduced blood flow can occur due to several factors such as compromised cardiac function, blood vessel constriction or blockage, or changes to local blood flow. Ischaemia is an important clinical consequence of many surgical and medical procedures and a variety of medical conditions including atherosclerosis which may lead to mesenteric ischemia.

The T-Stat system uses reflectance spectroscopy to measure the level of oxygen saturated haemoglobin in tissues (Figure 1). Oxygenated and deoxygenated haemoglobin have different absorption spectra under visible light, which can be used to calculate their relative concentrations. Visible light is used to illuminate a tissue through an optical fibre. Detection optical fibres gather the reflected light and pass it to a spectrophotometer where absorption is measured and the level of oxygen saturated haemoglobin in the tissue can be calculated. The T-Stat has several probes available for different applications including buccal or gastro-intestinal monitoring.



Figure 1 The T-Stat monitor with buccal probe and endoscopic catheter

Using the T-Stat monitor during various medical and diagnostic procedures would allow medical staff to assess the risk of ischaemia. If ischaemia is detected the medical specialist can take steps to alleviate the problem including the restoration of blood flow by removing clamps or by locating blood vessel blockages. This would prevent the serious consequences and associated morbidity caused by ischaemia.

CLINICAL NEED AND BURDEN OF DISEASE

Ischaemia due to many factors: acute or chronic disease, or surgical or medical procedures. As a result of this diversity of causes, data on the incidence and prevalence in Australia and New Zealand are lacking. Although ischaemia is a complication in many individual diseases or medical procedures, this data is not collated to give a global burden of ischaemia. To illustrate part of the burden of ischaemia an example is given for which some data exist. Intestinal ischaemia can occur subsequent to abdominal aorta surgery. There were 6,343 hospital separations in

2006-07 for abdominal aortic aneurysm in Australia. In a study investigating intestinal ischaemia after abdominal aorta surgery, it was found that up to 30 per cent of patients had ischaemia as detected by colonoscopic biopsy (Welch et al 1998). This is likely to be just a small part of the burden caused by ischaemia. Other areas where ischaemia detection may be important are cardiac surgery, gastrointestinal surgery, neonatal surgery.

DIFFUSION

No evidence was found of T-Stat usage in Australia.

COMPARATORS

Near infrared spectroscopy (NIRS) is used currently to assess the level of oxygen in tissues, however, this method lacks high quality diagnostic capabilities as normal ranges in tissues can be very broad. NIRS relies on an adequate blood flow, and may therefore fail under conditions of hypo-perfusion, which may be of importance as ischaemia may result from hypo-perfusion (Benaron et al 2004).

SAFETY AND EFFECTIVENESS ISSUES

Several studies have utilised the T-Stat system to monitor tissue oxygenation in a variety of procedures. In addition, the system has been widely evaluated in animal studies which are not included in this prioritising summary.

A preliminary study investigated the T-Stat in pigs and human subjects. The pig model was used for validation of the device. The human arm of the study investigated normoxia, hypoxia, and local ischaemia. Results are reported in Table 1 (Benaron et al 2004) (level IV diagnostic evidence).

Table 1 T-Stat determination of oxygen levels in various induced states

| T-Stat measurement | Oxygen levels ¹ |
|--------------------------------|----------------------------|
| <u>Normoxia</u> | |
| Enteric mucosal (n=50) | 69 ± 4 % |
| Skin (n=20) | 72 ± 16 % |
| Buccal mucosal (n=21) | 77 ± 3 % |
| <u>Hypoxia</u> | |
| Eosophageal mucosal (n=3) | 56 ± 6 |
| <u>Local ischaemia</u> | |
| Partial Finger occlusion (n=5) | 34* |

* SD not reported

The evaluation of the T-Stat for colon ischaemia diagnosis was documented in a case report of an endovascular aneurysm repair (EVAR). The T-Stat probe was introduced during a colonoscopy and basal colon mucosal oxygen saturation (CMOS) was determined to be 57 per cent. A test occlusion was performed to test for colonic

¹ Oxygen level are expressed as a percentage of oxygenated haemoglobin compared to total haemoglobin (oxygenated + deoxygenated haemoglobin)

ischaemia, which if evident would require the patient to undergo open surgery rather than EVAR. The CMOS did not drop to levels that would indicate colonic ischaemia and the abdominal aortic aneurysm (AAA) was successfully treated. The patient was monitored for two days and showed no signs of colonic ischaemia (Lee et al 2008) (level IV diagnostic evidence).

Another study investigating open or EVAR repair of AAA used the T-Stat system to monitor CMOS during surgery. There were 25 subjects in the study and both CMOS and buccal oxygen levels were measured. The buccal mucosal oxygen levels were used as a comparator to verify the CMOS values were truly local values and not a reflection of systemic oxygen levels. The average recovery time to baseline after the procedures were completed was 6.4 ± 3.3 mins. Colonic ischaemia was not detected during or after the procedure. Results are shown in Table 2 (Lee et al 2006)(level IV diagnostic evidence).

Table 2 T-Stat determined oxygen levels during various procedures

| T-Stat measurement | Oxygen level ² (n=25) |
|---|----------------------------------|
| Baseline CMOS | 55.8 ± 8.0 % [*] |
| Test CMOS | 25.7 ± 17.4 % (p < 0.001) |
| Post-test CMOS | 56.5 ± 10.3 % [*] |
| Pre-surgical baseline CMOS | 56.0 ± 9.2 % [#] |
| Surgical CMOS | 14.8 ± 18.6 % (p < 0.0001) |
| Post-surgery CMOS | 55.7 ± 5.7 % [#] |
| Buccal mucosal oxygen levels at all times | 82 ± 6 % [§] |

* Not significantly different, # Not significantly different and dropped to 64 ± 5 % in two patients with significant bleeding

The evidence on the T-Stat is preliminary in that it lacks longer term outcomes. Studies comparing populations that do and do not receive diagnosis using the T-Stat are needed to see if use of the device provides a benefit over current methods of ischaemia management. Despite this the studies show that important local information about oxygenation is provided by the T-Stat monitor and this fulfils a gap in current monitoring capabilities.

COST IMPACT

Endovations Pty Ltd intends to market the T-Stat monitoring device in Australia and propose to launch the product in April 2009 at the Perinatal Society of Australia and New Zealand meeting in Darwin. The approximate Australian market price for the monitor alone is \$AUD 40,000 (depending on individual negotiations and exchange rates). The price for the one-use consumables has not been finalised as yet. T-Stat training will be provided by a team of medical specialists from Endovations (personal communication: Endovations).

² Oxygen level are expressed as a percentage of oxygenated haemoglobin compared to total haemoglobin (oxygenated + deoxygenated haemoglobin)

