**Introduction**

Ultrasonic surgical systems that use high-frequency sound waves to cut and coagulate tissue have been in use for about ten years. These systems include the B.U.S. Endotron (Medicamat), which is used in general surgery, plastic surgery and lipoaspiration; the AutoSonix System (US Surgical), which includes the "Ultra Shears" instrument for cutting; the SonoSurg (Olympus); and the Harmonic Scalpel® (Ethicon Endo-Surgery, Inc./Johnson & Johnson). The technology is often referred to by various names including: harmonic scalpel, ultrasonic scalpel, ultrasonic dissector, harmonic shears, harmonic coagulating shears, harmonic scissors, ultrasonic shears or "Ultracision" (this term is no longer used by Johnson & Johnson in connection with the Harmonic Scalpel).

According to the Johnson & Johnson web site the Harmonic Scalpel "vibrates at more than 55,000 times per second and is used in less-invasive videoscopic and open surgical procedures such as gallbladder removal, hernia repair, hysterectomy, bladder neck suspension for urinary stress incontinence and gastroesophageal anti-reflux surgery to treat chronic heartburn." The system is intended to lessen tissue damage during surgery and is "...indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to, or substitute for, electrocautery, lasers and steel scalpels." Further information from the manufacturer states that the device is a "...multifunctional instrument that simultaneously cuts tissue and seals blood vessels, and provides the potential for reduced tissue damage in patients. Combined with videoscopic surgery, the ultrasonic device can mean faster recovery and less patient scarring."

The Harmonic Scalpel and the Autosonix System are both licensed by Health Canada. According to the manufacturer, the Harmonic Scalpel has been available in Canada for about five years. The Canadian list price for the Harmonic Scalpel system is $32,504 for the generator, $1,812 for the footswitch and cable assembly, and approximately $2,000 for a box of disposable blades (these come in various shapes and sizes). A one-year extended warranty on the generator is $1,500 (Dave Ames, Johnson & Johnson, personal communication, 2002 October 22). The SonoSurg system has recently been launched in the US and Latin America.
Research Questions

The main questions surrounding the use of ultrasonic cutting and coagulating devices are:

1. What are the benefits of this technology, e.g. reductions in tissue damage, blood loss and scarring in surgical patients?
2. For which surgical procedures is there evidence of benefit?
3. Is the use of this technology cost-effective, e.g. through reductions in surgical procedure time, patient recovery time and length of hospital stay?
4. Are there issues or adverse effects associated with the use of this technology?

Literature Search

Preliminary literature searches were run on the PubMed, The Cochrane Library and the CRD (HTA, DARE and NHS EED) databases. The web sites of additional HTA agencies were scanned per the CCOHTA literature search checklist. The literature searches covered from 1998 to October 2002.

Summary of Findings

No systematic reviews or health technology assessments were identified. Most of the studies found reported specifically on the Harmonic Scalpel (Johnson & Johnson product). Only a few papers reported on other ultrasonic surgical systems.

The Australian Safety and Efficacy Register of New Intervenotional Procedures - Surgical (ASERNIP-S) NET-S Database of Procedures (http://www.racs.edu.au/asnrip-s_net-s/procedures.htm) classifies tonsillectomy with the harmonic scalpel as an "evolving technique". Other studies and reviews have been published reporting on different surgical procedures using ultrasonic devices, for example:

- laparoscopic hysterectomy
- laparoscopic lymph node dissection / lymphadenectomy
- Nissen fundoplication
- radial artery harvesting
- thyroid surgery
- tonsillectomy
- transanal endoscopic microsurgery (for rectal carcinoma)
Many earlier (pre-1998 papers) describe experiences with further types of surgery, including laparoscopic cholecystectomy, splenectomy and colectomy.2

Conclusions

There may be sufficient information in the published literature to allow for an assessment of the use of ultrasonic cutting and coagulation devices in some types of surgery, for example, in tonsillectomy. It may only be possible to discuss the Harmonic Scalpel in such an assessment, as there appears to be little in the published literature regarding the other systems.

References


