Australian Government

Department of Health and Ageing

Horizon Scanning Technology Prioritising Summary

Laser tissue welding using a protein-based solder

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ASERNIP-S

Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

Royal Australasian College of Surgeons

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This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

NAME OF TECHNOLOGY:
Laser tissue welding using protein-based solder.

PURPOSE & TARGET GROUP:
This procedure enables the repair of vessels without sutures. Therefore, it may be widely applicable, especially in ophthalmology, urology and vascular surgery.

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☑ Experimental
- ☐ Investigational
- ☐ Nearly Established
- ☐ Established
- ☐ Established but changed indication or modification of technique
- ☐ Should be taken out of use

No device is listed or registered in the Australian Register of Therapeutic Goods that is capable of functioning as a protein-based solder.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
USA	✓		

IMPACT SUMMARY

Background:
Sutures are predominantly utilised for procedures requiring the joining of two vessel ends.[1] The new process of laser tissue welding, using a protein-based solder, joins vessel ends without requiring sutures, resulting in "sutureless surgery".

The human albumin–based solder incorporates indocyanine green dye resulting in an optimal absorption of laser wavelength of approximately 810nm, effectively fusing the outer edges of the wound surface without penetrating to deep tissue.[2]

It has been shown that laser welding is a quick, reliable method for the repair of blood vessels. The protein-based solder utilised for this procedure is not only resorbable, but is thought to eventually provide a tensile strength greater than that of normal sutures, and to have a lower complication rate than traditional suturing.[3]

Clinical need and burden of disease:
Suturing has several detrimental aspects; the penetrating needle can induce vascular wall damage, and the non-absorbable suture material can cause an inflammatory response. An

inflammatory response can also lead to thrombocyte aggregation or intimal hyperplasia, resulting in stenosis.[1]

Estimated speed, geographic and practitioner use patterns of diffusion in the health system:

Kirsch and colleagues first published phase I clinical trial results of laser tissue welding using a protein-based solder in August 1995, with results from a comparative study published in 1997. The Australian Federal Government has donated $250,000 for the development of a similar Australian product by Avastra, which will commence clinical trials early 2004, under the direction of Dr Peter Maitz.[5]

Existing comparators:

Traditional nylon sutures

Estimated cost impact:

The costs associated with this new product are not available. The cost of traditional suturing repair in Australia is also not available. However, the reimbursement cost as stated by the Medicare Benefits Schedule for the traditional repair using microsurgical techniques, for restoration of continuity of artery or vein is estimated to be approximately $906.[6]

Efficacy and safety issues:

Short-term safety and efficacy data exist from two non randomised comparative studies (evidence level III-2)[7] and one case series (evidence level IV)[7]. Most studies were conducted using a protein-based solder containing human albumin concentrations of approximately 50%, which has been shown to achieve optimal tensile strength.[8]

Study details	Key efficacy findings	Key safety findings
Comparative study		
Kirsch *et al.*[2] 1997, USA 36 Patients Follow up: 3 months to 3 years Laser Tissue Welding (LTW) (n=25) Suture group (n=11) *Selection Criteria:* Urethral Surgery		No strictures or diverticule resulted in suture or LTW groups. No patients in suture or LTW groups experienced wound infection or poor wound healing.
Kirsch *et al.*[4] 2001, USA 138 Patients Age range: 6 months to 34 years, mean 15 months Follow up: Mean 12 months (min 6 months, max 22 months) Laser tissue welding (LTW) (n=54) Suture (n=84) *Selection Criteria:*	Mean operating times were significantly shorter in LTW (mean 5.1±0.3 (SD)min) compared with suture group (mean 26.7±1.7 (SD) min) (P<0.001). Mean number of sutures in laser tissue welding patients required for tissue alignment was significantly less (mean 8.2±0.6	The complication rate appears to be lower in LTW (2/54 (3.7%) fistulas) compared with suture group (7/84 (8.3%) fistulas and 2/84 (2.4%) meatal stenosis).

Hypospadias repair	(SD)) compared with the suture group (mean 23.2±1.5(SD)) (P<0.001).	
Case Series		
Kirsch *et al.*[3] 1995, USA 10 Patients Age range: 3 months to 38 years, mean 8 years. Follow Up: mean 7.1±2.2 months Laser tissue soldering (LTW) *Selection Criteria:* Urinary tract reconstruction	Where standard microsuture repair preceded laser-soldered suture line reinforcement, mean intraoperative leak pressure was (mean 94.2±24.2 (SD) mmHg) significantly higher than in sutured patients where no laser-solder reinforcement was preformed (mean 20±2.8 (SD) mmHg) (P<0.001).	Disruption to alignment sutures occurred in 2/10 (20%) patients on laser activation. No intraoperative or postoperative complications.

There is a small evidence base for the safety and efficacy of laser tissue welding as an alternative to traditional suturing. However, the studies conducted have indicated that laser tissue welding may enable a stronger repair of vessels with reduced complication rates and operative time.

Ethical issues: The solder material contains human albumin protein, which potentially could be an ethical issue as the source of the material is not stated.

Cultural or religious considerations: Not applicable

Other issues:
The same research group conducted all studies, on which the safety and efficacy of laser tissue welding are based.

Conclusion:
Limited evidence exists on the safety and efficacy of laser tissue welding using protein-based solder. Long-term safety and efficacy data from randomised controlled trials may be required before this procedure can be widely accepted.

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SOURCES OF FURTHER INFORMATION:

Maitz PK, Trickett RI, Dekker P, Tos P, Dawes JM Piper JA, Lanzetta M, Owen ER. Sutureless microvascular anastomoses by a biodegradable laser-activated solid protein solder. *Plastic Reconstructive Surgery* 1999 Nov; **104**(6):1726-31.

SEARCH CRITERIA:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register International, Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in January 2004.

Search terms used were: ‘tissue welding’, ‘protein solder and tissue welding’, ‘laser welding’ and ‘sutureless surgery’