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Australia and New Zealand Horizon Scanning Network

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Horizon scanning prioritising summary

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Extracorporeal shock wave therapy: For the treatment of chronic calcifying tendonitis of the rotator cuff.

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PRIORITISING SUMMARY

REGISTER ID: 0000010

NAME OF TECHNOLOGY: EXTRACORPOREAL SHOCK WAVE THERAPY

PURPOSE AND TARGET GROUP: EXTRACORPOREAL SHOCK WAVE THERAPY FOR THE TREATMENT OF CHRONIC CALCIFYING TENDONITIS OF THE ROTATOR CUFF

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|---|-------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 71920 |
| <input type="checkbox"/> No | <input type="checkbox"/> Not applicable | |

Several units are available in Australia and are registered on the TGA. Gyrus Australasia Pty Ltd distribute the Swiss DolorClast for the use of extracorporeal shock wave therapy.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Germany	✓		
England	✓		
Taiwan	✓		
France	✓		
United States			✓
Australia		✓	

IMPACT SUMMARY:

Sports medicine centres in Australia, such as South Sydney Sports Medicine, provide radial shock wave therapy for the non-invasive treatment of tendonitis. In Australia, the technology is available through sports medicine clinics for persons with a diagnosis of tendonitis and chronic shoulder pain. Patients who are pregnant, wear a pacemaker or take anticoagulants are not normally treated with this technology (Charrin & Noel 2001).

Shoulder tendonitis is a common source of shoulder pain. In the 1999-2000 *Bettering the Evaluation and Care of Health* (BEACH) report shoulder complaints comprised 0.7% of all reasons for an encounter with a General Practitioner, or 1 in every 100 complaints (Britt et al). Calcific tendonitis results primarily from overuse of the arm or from an acute strain. It is characterised by the deposition of calcium salts within a tendon. The exact mechanism for this

process is not known but may be initiated by ischaemia or degeneration of the tendon (2001). Approximately 50% of patients with calcific tendonitis experience shoulder pain, which can be quite severe and result in significant limitation in activities of daily living (Pan et al 2003).

Shock wave therapy involves the application of pressure waves to a specific site in the body (Ortho Shock Wave Consultants 2004). The pressure waves are high positive waves of up to 100 times that of atmospheric pressure. The pressure waves travel through fluid and soft tissue and interact where there is a change in impedance such as at a tissue-bone interface. A more common use of this technology is to break up kidney stones into fragments that can then be passed in the urine.

In the treatment of calcific tendonitis of the shoulder the pressure waves are believed to induce fragmentation of calcium deposits and stimulate their resorption (Daecke et al 2002). The low energy form of these waves are believed to relieve pain while high-energy waves have been found to increase regional blood flow, produce capillary lesions and growth of new capillaries (Charrin & Noel 2001). Conventional treatment for this condition involves physiotherapy, analgesics and sub-acromial injections of steroids (Schmitt et al 2001) or in chronic cases, arthroscopic surgery to remove the calcification (Daecke et al 2002).

Several good quality studies have been performed to establish the efficacy or effectiveness of this technology for calcific tendonitis of the shoulder. In a multi-centre, double blind placebo randomised-controlled trial, 144 patients with calcific deposits of at least 5 millimetres in diameter and symptoms of pain and tenderness for at least 6 months received 2 treatments 2 weeks apart of 1) high energy extracorporeal shock wave therapy (ESWT), 2) low energy ESWT or 3) sham treatment (Gerdesmeyer et al 2003). Shoulder function was assessed on a 100 point scale (Constant and Murley Scale, CMS) reported to have high reliability. Pain using a 100 mm visual analogue scale (VAS) was assessed, as were adverse events. The patients were evaluated at 3, 6 and 12 months after treatment. Patients in both the low and high energy ESWT showed significantly better CMS scores at all measurement points compared to sham treatment. Self-rated pain was also significantly better in the ESWT groups compared to sham. Adverse events consisted of pain during treatment (42 moderate pain, 21 severe in ESWT patients, 25 sham patients) and bleeding or haematoma directly after treatment in 68 ESWT patients and 8 in the sham treatment.

In another randomised controlled trial of 60 patients with continuous shoulder pain for 6 months or more, the effectiveness of ESWT (2 treatments 14 days apart) was compared with transcutaneous electric nerve stimulation (TENS, 3 times per week for 4 weeks) (Pan et al 2003). Outcome measures were the CMS score, VAS manual muscle test and the sonographic evaluation of calcium deposit shape and size. Measures were taken at baseline, and at 2, 4 and 12 weeks post-therapy. The CMS score and VAS improved significantly in the ESWT treated group compared to TENS group at the 2, 4 and 12 week follow-ups, as did the reduction in size of calcium deposits at the 4 and 12 week timepoints. Five patients complained of soreness after ESWT but no other side effects (eg bruising) were noted.

In one other long-term RCT of high versus low energy shockwave therapy, successful treatment occurred in 70% of patients from either therapy at 4-year follow-up (Daecke et al 2002). No long-term complications were reported.

Several different therapy units are available for use in Australia and are registered with the Therapeutic Goods Administration (under the UMDNS Code and Description 11248). The unit cost of the Swiss DolorClast (Urology Solutions Pty Ltd, Australia) is approximately \$40,000. This procedure attracts a per treatment charge to the patient of \$55 and is not currently

reimbursed by Medicare. A consultation fee for a medical practitioner (sports physician) is also charged at the assumed rate of \$13.80 (MBS #444) (MBS 2002).

CONCLUSION:

There are several good quality studies describing the effectiveness of extracorporeal shock wave therapy for the treatment of shoulder tendonitis. In addition, it is expected that there would be a rapid uptake of this technology based on the prevalence of the condition.

HEALTHPACT ACTION:

It is therefore recommended that a Horizon Scanning report be conducted.

SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA TO BE USED:

Chronic Disease

High-Energy Shock Waves/*therapeutic use

*Rotator Cuff/pathology/radiography

Shoulder/*pathology/radiography

Tendinitis/*therapy

Calcinosis/complications/physiopathology/*therapy/ultrasonography

Tendinitis/complications/physiopathology/*therapy/ultrasonography/pathology

Transcutaneous Electric Nerve Stimulation/methods/standards