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Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

0.2-0.5 Tesla MRI for the detection of arthritis and musculoskeletal disease

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PRIORITISING SUMMARY (UPDATE 2009)

REGISTER ID: **000371**

NAME OF TECHNOLOGY: **0.2-0.5 TESLA MRI**

PURPOSE AND TARGET GROUP: **FOR THE DETECTION OF ARTHRITIS AND MUSCULOSKELETAL DISEASE**

2009 SAFETY AND EFFECTIVENESS ISSUES

A small, cross-classification study compared the diagnostic capabilities of two low-field MRI units (0.2T portable MV1000 MagneVu[1] and the 0.2T Esaote Biomedica Artoscan) compared to conventional radiography (CR) and CT (level II diagnostic evidence). Twenty patients with clinically confirmed rheumatoid arthritis (RA) of the hand and wrist (median disease duration 9 years, range 0-15 years), and five controls were enrolled. All RA patients were being treated with anti-rheumatic drugs including corticosteroids. All readers of images were blinded to the clinical diagnosis of the subjects and to the findings of other imaging modalities, however, CT, MRI and X-ray images were evaluated by different readers. CT was considered to be the diagnostic reference standard[2]. Bone erosions of the wrist joint and the second to the fifth metacarpophalangeal (MCP) joints of one hand were imaged with all modalities over a 2-week time-period (Duer-Jenson et al 2009).

The Artoscan MRI unit allowed complete visualisation of the second to the fifth MCP joints and the entire wrist joint area. However the reduced field of view (FOV) of the MagneVu gave incomplete visualisation of the MCP joints (84% bones visualised entirely and 16% of bones only 67-99% visualised) and wrist joints (31.6% visualised entirely, 37.9% were 67-99% visualised and 19.7% not visualised at all). It should also be noted that examination time for each subject with the Artoscan was six minutes compared to 45 minutes for the MagneVu.

In the MCP joints, CT, Artoscan, MagneVu and CR detected a total of 39, 29, 22 and 18 bones with one or more erosions, respectively. Compared to CT, the Artoscan MRI performed better than other imaging modalities with a sensitivity, specificity and accuracy of for all MCP joints (metacarpal head plus phalangeal base) of 68, 94 and 90 per cent, respectively. As expected, in comparison, the MagneVu had a poor sensitivity (54%) due to the reduced FOV, but good specificity (93%) and reasonable accuracy (88%). CR had a sensitivity, specificity and accuracy of 57, 99 and 93 per cent, respectively. When examining the wrist joints, CT, Artoscan, MagneVu and CR detected a total of 157, 87, 33 and 27 bones with one or more erosions, respectively.

[1] The company which manufactured the MagneVu is no longer operational. However, the MagneVu is used in the majority of studies reporting on the use of low-field MRI for monitoring RA

[2] CT is not usually considered to be the appropriate reference standard for assessing RA

The sensitivity of all modalities was low when compared to CT: 53, 28 and 34 per cent for Artoscan, MagneVu and CR, respectively. The corresponding specificities for the three modalities were 94, 93 and 99 per cent, and accuracy values were 90, 88 and 93 per cent, respectively. Although overall the Artoscan performed better than the other modalities when compared to CT, CR was better at identifying erosions in the phalangeal bases (78% sensitivity compared to 56% for the Artoscan). Compared to studies reported in the 2008 prioritising summary, this study has demonstrated a relatively poor performance of low-field MRI for the detection of bone erosions (Duer-Jenson et al 2009).

A 2007 study overlooked in the original prioritising summary, reported on the use of the MagneVu low-field MRI and CR for the detection of bone erosions in RA patients, using high-field MRI as a reference standard (level III-2 diagnostic evidence). The hands and wrists of 15 patients with clinically confirmed, severe RA (median disease duration 11 years) all being treated with leflunomide were imaged. High-field MRI identified 70 erosions of which low-field MRI identified 32 and CR four. The sensitivity, specificity and accuracy of low-field MRI was 46, 94 and 55 per cent, respectively, and the corresponding values for CR were 6, 100 and 23 per cent, respectively. As noted in the study by Duer-Jenson et al, the MagneVu has a restricted FOV and is not capable of imaging all bony sites. High-field MRI identified erosions in 81 per cent of bony sites compared to 21 and nine per cent for low-field MRI and CR, respectively (Freeston et al 2007).

However, low-field MRI may be of greatest clinical use in the monitoring of treatment over time by the targeted imaging of specific erosions. Olech et al (2008) imaged 44 patients with RA (disease duration < 2 years) using low-field MRI and CR. The number of erosions was identified at baseline. Twenty patients were re-imaged at six-months. At baseline, low-field MRI of one hand identified 34/44 (77%) of patients with erosions, MRI of two hands 39/44 (89%) and two hands and feet 40/44 (91%). At six-months, low-field MRI of one hand identified an increase in the number of erosions in 10/20 (50%) of subjects, imaging of two hands and imaging of two hands and feet identified an increase in 11/20 (55%) subjects. The authors concluded that low-field imaging of two hands could be used to establish baseline numbers of erosions and that the monitoring of disease progression over time could be achieved by imaging one hand (level IV diagnostic evidence).

The above studies all discuss the identification and/or monitoring of bone erosions in RA patients, however one important aspect of RA patient assessment is the ability to monitor synovitis[3]. A contrast agent, such as gadolinium (Gd) is usually required to assess synovitis using MRI. To avoid the use of Gd, low-field MRI can utilise a

[3] Synovitis is inflammation of a synovial membrane. It is usually painful, particularly on motion and is characterised by a fluctuating swelling due to effusion within a synovial sac.

method referred to as STIR, which uses a pulse sequence to suppress the MRI signal from fat. Using this technique image quality may be reduced due to the low signal-to-noise ratio (Freeston et al 2008). Ostergaard et al (2009) imaged the wrists and MCP joints of 45 patients with RA and nine controls using unenhanced images (no Gd) low-field MRI (Artoscan) with conventional Gd-MRI as the reference standard (level III-1 diagnostic evidence). Images were assessed for bone erosion and synovitis.

The sensitivity, specificity and accuracy of –Gd low-field MRI for the detection of erosions was 93, 99 and 97 per cent, respectively. However, the sensitivity, specificity and accuracy of –Gd low-field MRI for the detection of synovitis was 60, 96 and 76 per cent, respectively.

2009 SUMMARY OF FINDINGS:

Although low-field MRI is not as sensitive as high-field MRI, it does have several advantages including access, affordability and patient tolerance. The use of low-field MRI instead of x-rays for the monitoring of a patient's progress has the advantage that patients are not exposed to high, cumulative levels of ionising radiation, however long image acquisition times remain an issue to be considered. It would also appear that the type of low-field MRI unit that is used for patient assessment is of importance, as those with a restricted field-of-view are less sensitive.

2009 HEALTHPACT ACTION:

As low-field MRI is already in limited use in Australia and has demonstrated that it is useful in the monitoring of patient treatment progression, it is therefore recommended that this report be disseminated to relevant clinical colleges and further research is no longer warranted into this technology.

2009 NUMBER OF INCLUDED STUDIES

Level II diagnostic evidence	1
Level III-1 diagnostic evidence	1
Level III-2 diagnostic evidence	1

2009 REFERENCES:

Duer-Jensen, A., Ejbjerg, B. et al (2009). 'Does low-field dedicated extremity MRI (E-MRI) reliably detect bone erosions in rheumatoid arthritis? A comparison of two different E-MRI units and conventional radiography with high-resolution CT scanning', *Ann Rheum Dis,* 68 (8), 1296-1302.

Freeston, J. E., Bird, P. & Conaghan, P. G. (2009). 'The role of MRI in rheumatoid arthritis: research and clinical issues', *Curr Opin Rheumatol,* 21 (2), 95-101.

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contrast injection -- Does it change the assessment of inflammatory and destructive joint changes by the OMERACT RAMRIS?', *J Rheumatol*, 36 (8), 1806-1810.

Schiff, M. H., Hobbs, K. F. et al (2007). 'A retrospective analysis of low-field strength magnetic resonance imaging and the management of patients with rheumatoid arthritis', *Curr Med Res Opin*, 23 (5), 961-968.

PRIORITISING SUMMARY (2008)

REGISTER ID: **000371**

NAME OF TECHNOLOGY: **0.2-0.5 TESLA MRI**

PURPOSE AND TARGET GROUP: **FOR THE DETECTION OF ARTHRITIS AND MUSCULOSKELETAL DISEASE**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	92846, 147022
☐	No		
☐	Not applicable		

Two units have TGA approval and are described as MRI systems for extremity imaging with a permanent magnet. One is sponsored by Medtronic Australia Pty Ltd (ARTG 92846), however it appears that Medtronic currently do not distribute this scanner in Australia. The other unit, the ESAOTE-G scanner is distributed by Biolab Australia Pty Ltd (ARTG 147022).

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Denmark	✓		
United States	✓		

IMPACT SUMMARY:

Several units of low-field magnetic resonance imaging (MRI) are manufactured for the purpose of identifying individuals with early symptoms of bone and joint disease. The technology would be made available through general practitioners, outpatient clinics and hospitals.

2008 BACKGROUND

MRI scanners are ideal for imaging soft tissues in the body as they use a pulsed oscillating magnetic field to affect the magnetic behaviour of hydrogen nuclei in the

body. Not only is MRI sensitive to differing signals from one tissue compared to another, but is sensitive to changes in the hydrogen concentration within tissues and fluids. When tissue is placed in a magnetic field and a radio-frequency is applied, the alignment of the hydrogen nuclei changes so that they are oscillating perpendicular to the main field direction (excitation). Once the pulse is removed, the realignment, or relaxation, of the nuclei is slower due to the effect of the constant magnetic field exerted by the MRI scanner. The relaxation time is referred to as T1. Hydrogen nuclei in blood and cerebrospinal fluid have a long relaxation time, compared to nuclei in tissues, with hydrogen nuclei in fat cells having the shortest relaxation time of approximately 300 milliseconds. The differences in realignment and spin times appear as differences in brightness on the MR image (FASEB 2007).

The rate of relaxation will depend on the strength of the constant magnetic field (FASEB 2007). Magnetic field strength is expressed units of Tesla (T). The strength of magnets may vary: ultra-high field (4.0 to 7.0 T, mostly used for research); high field (1.5 to 3.0 T); mid field (0.5 to 1.4 T); low-field (0.2 to 0.4 T); and ultra-low field (less than 0.2T). In addition, there are three main types of magnet design: permanent magnets which are suited to open scanners (0.2 T) and cannot be turned off; resistive magnets, which use an electric current running through a coil to produce a magnetic field; and superconducting magnets. The majority of MRI scanners use superconducting magnets, which operate at such low temperatures that resistance is negligible, allowing strong electric currents, and hence high magnetic fields, to be generated without generating heat (Hashemi et al 2004).

MRI has been proposed as a suitable method for the early detection and diagnosis of joint diseases, including rheumatoid arthritis. Low-field MRI scanners (0.2 T) are considered to be ideal for assessing the extremities such as hands and peripheral joints. Low-field MRI scanners are open and are therefore considered to be more comfortable for patients, especially those who may be claustrophobic, compared to high field scanners. In addition, the purchase price of low-field MRI scanners is lower compared to conventional scanners (Lindegaard et al 2006).

2008 Clinical Need and Burden of Disease

Reliable incidence and prevalence data for arthritis and musculoskeletal conditions are lacking in both Australia and New Zealand. Prevalence data in particular are generally ascertained from health surveys, which rely on self reported data and are therefore estimations of the true prevalence of disease. Arthritis and musculoskeletal conditions are one of the most common reported chronic conditions in Australia and New Zealand.

In the 2001 Australian National Health Survey 32.3 per cent of respondents reported arthritis or a musculoskeletal condition lasting longer than six months. This number equates to approximately six million Australians experiencing chronic illness or pain from arthritis, back pain, osteoporosis, osteoporotic fractures as well as

musculoskeletal and connective tissue diseases. Approximately 13.3 and 1.3 per cent of the total population reported having arthritis and rheumatism, respectively, in 2001 (AIHW 2005).

In 2005, Access Economics reported on the prevalence of arthritis conditions in New Zealand. Data were obtained from the Ministry of Health's New Zealand Health Survey (NZHS), which summarises *self-reported* prevalence data. In addition, prevalence data from a primary care survey were included (Table 1). Raw prevalence data for all types of arthritis are shown in Figure 1 (Access Economics Pty Ltd 2005).

Table 1 Prevalence rates of arthritis in New Zealand

	Osteo-arthritis (%)	Rheumatoid arthritis (%)	All forms arthritis (%)	All forms musculoskeletal disorder (%)
NZHS community based study, 2003	7.7	3.2	15.7	32.7
Taylor et al (2004) primary care based study, 2003	1.44	0.79	3.75	20.4
Colmar Brunton community based study, 2003	n/a	n/a	n/a	24.6

(Access Economics Pty Ltd 2005)

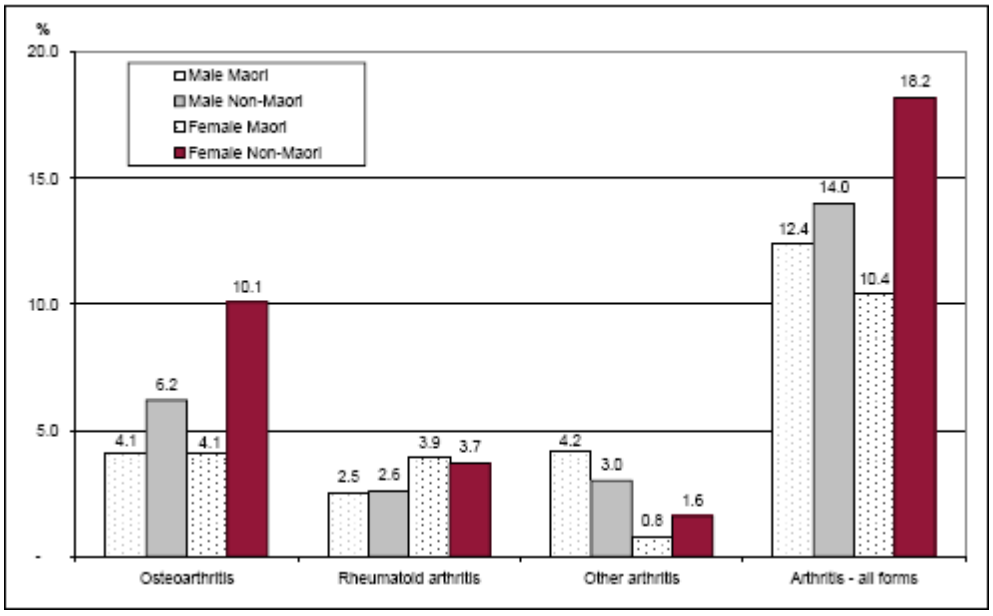

Figure 1 Raw prevalence rates by type of arthritis, New Zealand 2003 (Access Economics Pty Ltd 2005)

Arthritis is associated with increasing age, therefore with the ageing of the population it may be expected that the prevalence of this condition may increase.

2008 DIFFUSION

Biolab Australia Pty Ltd currently distributes the ESAOTE-G 0.27 tesla MRI scanner in Australia. There are at least three units operating in Australia (Albury, Newcastle and St George Private Hospital, Sydney, NSW). These units are currently used for a mixed clientele of physiotherapy, chiropractic, orthopaedic and general practice patients (personal communication Biolab Australia Pty Ltd).

2008 COMPARATORS

Rheumatoid arthritis is diagnosed using a combination of clinical observation and laboratory testing. The disease is difficult to diagnose in its early stages and symptoms can vary enormously between patients and may overlap with symptoms of other forms of arthritis and joint disease. The American College of Rheumatology developed a set of criteria for the diagnosis of RA, where four out of seven signs and symptoms are required for a firm diagnosis (Table 2).

Table 2 American College of Rheumatology rheumatoid arthritis diagnostic criteria

Criteria		Comment
1	Morning stiffness	Duration > 1 hour; lasting > 6 weeks
2	Arthritis of at least 3 areas	Soft tissue swelling or exudation lasting > 6 weeks
3	Arthritis of hand joints	Wrist, metacarpophalangeal joints or proximal interphalangeal joints lasting > 6 weeks
4	Symmetrical arthritis	At least one area, lasting > 6 weeks
5	Rheumatoid nodules	As observed by a physician
6	Serum rheumatoid factor	As assessed by a method positive in less than 5% of control subjects
7	Radiographic changes	As seen on anteroposterior films of wrists and hands

Source: (AIHW 2005)

2008 SAFETY AND EFFECTIVENESS ISSUES

Three studies, which were conducted on patients with rheumatoid arthritis (RA) of the hand, fingers or wrist, were identified for inclusion in this Prioritising Summary. A clinical trial, where patients (n=130) diagnosed with early symptoms of RA were randomised to a treatment regime, then disease progression was monitored with X-ray and 0.2 and 1.0 T MRI at baseline, 6 and 12-months, was excluded as the MRI results were not differentiated from each other (Hetland et al 2008). One study used 0.2 T to assess patients suspected of cervical spondylotic myelopathy, however no comparative scanning modality was used (Hori et al 2006). In addition, low-field MRI (0.2 T) has been used to scan women at high risk of breast cancer and to guide corticosteroid injections into the sacroiliac joints of patients with spondylarthropathy (Gunaydin et al 2006).

The diagnostic capabilities of low-field MRI (0.2 T), high field MRI (1.0 T) and conventional X-ray were compared in 37 patients clinically confirmed to have RA[4] and 28 controls (Ejbjerg et al 2005). The same radiologist or clinician performed all

[4] Median disease duration 5 years, range 1-37 years

evaluations, which were blinded to the results of the evaluations by other modalities. High field MRI was considered to be the reference standard. Images were assessed for the presence of bone erosion, synovitis and bone marrow oedema. The sensitivity, specificity and accuracy of low-field MRI for bone erosion were 94, 93 and 94 per cent, respectively, compared to the corresponding values of 33, 98 and 83 per cent for conventional X-ray. The sensitivity, specificity and accuracy of low-field MRI were high when used to diagnose synovitis at 90, 96, and 94 per cent. However the sensitivity was poor when low-field MRI was used to diagnose bone marrow oedema (39%) with high specificity (99%) and accuracy (95%). The significance of this finding is unclear as the position of bone marrow oedema in the progression of RA disease has not been resolved. If the presence of bone marrow oedema is an interim phase between the presence of synovitis and bone erosion, then the low sensitivity of low-field MRI may have little impact. The intraclass correlation coefficients between low and high-field MRI scores were 0.923 ($p<0.05$) for synovitis and 0.936 ($p<0.005$) for bone erosions (level II diagnostic evidence).

A small-scale study, conducted on 24 consecutive patients with clinically confirmed RA of less than 12-months duration monitored patients at baseline and after 6 and 12 months of methotrexate treatment (Lindegaard et al 2006). Patients were monitored with clinical and biochemical examinations, 0.2 T MRI and X-ray. MRI assessors were blinded to the clinical and radiographic findings. Images were assessed for the presence of bone erosion, synovitis, tenosynovitis[5] and bone marrow oedema. At the end of 12-months treatment both the erythrocyte sedimentation rate and C reactive protein levels in all patients were significantly reduced ($p=0.002$). At baseline, X-ray detected 15 bone erosions in six patients, compared to the 21 bone erosions detected by MRI in 10 patients. One erosion, detected by X-ray, was not detected by MRI, however only six (29%) of the MRI erosions were detected by X-ray. At 12-months, X-ray detected 17 bone erosions in seven patients, of which eight were new erosions and six detected at baseline were no longer visible. X-ray progression of disease therefore occurred in five patients. MRI detected 15 new erosions in eight patients at 12-months follow-up and only one of the baseline erosions was no longer visible. Four (19%) of the bone erosions visible on MRI progressed to being visible by X-ray at 12-months. The median MRI synovitis score at baseline was eight (range 4-11), which was reduced significantly at 12-months to four (range 0-7) ($p<0.001$). Baseline scores for bone oedema and tenosynovitis were zero (range 0-1.5 and 0-0.25, respectively). These values remained unchanged over the course of the 12-month treatment. However, joints with mild synovitis MRI detected at baseline had a relative risk of 7.3 of having bone erosions detected by MRI at 12-months compared to joints which were synovitis free at baseline. For joints with severe synovitis at baseline, this relative risk increased to 10.7. The number of new bone erosions detected by MRI at 12-months correlated significantly with the baseline synovitis score (r=0.61,

[5] Tenosynovitis = inflammation of a tendon sheath

$p<0.001$). From these results it appears that low-field MRI is effective in the preliminary diagnostic investigation of patients with *early* symptoms of RA (level II diagnostic evidence).

A similar study compared the use of high (1.0 T) and low-field (0.2 T) MRI and conventional radiography to monitor 18 consecutive patients[6] with confirmed RA who were undergoing therapy. Results from all screening modalities were assessed independently by two reviewers (Taouli et al 2004). No significant difference was reported in the ability of high or low-field MRI to detect bone erosions (27.5 ± 9.8 and 28.8 ± 10.0, respectively) ($p=0.71$). However, both high and low-field MRI detected significantly higher numbers of bone erosions compared to X-ray (13.1 ± 8.3) ($p<0.001$). Similarly there was no statistically significant difference between the joint-space narrowing scores obtained with high and low-field MRI (15.2 ± 8.3 and 14.5 ± 10.4, respectively). Although these scores were slightly higher than those obtained with X-ray (12.7 ± 9.6) there was no statistically significant difference ($p=0.70$). In addition, scores obtained with all modalities had high standard deviations indicating a great deal of variation in the small patient group. There was no difference in synovitis scores obtained with high and low-field MRI ($p=0.14$). The inter-observer agreement for MRI scores was good to excellent with correlations of 0.83 to 0.94 (level III-2 diagnostic evidence).

2008 Cost Impact

A complete ESAOTE-G 0.27 tesla MRI scanner (scanner, cage plus software) currently costs $875,000 plus GST. This price does not include the cost of a laser printer for films which may cost up to $15,000. As these scanners use a permanent magnet they do not require expensive cryogenic capabilities and have low daily running costs (2 kW versus 1000 kW for conventional MRI scanners). The patient must bear the full cost of a scan with a low-field MRI scanner as the Medicare Benefits Schedule currently reimburses only scans performed on scanners that are greater than, or equal to, 1.5 tesla (personal communication Biolab Australia Pty Ltd).

2008 Ethical, Cultural or Religious Considerations

No issues were identified/raised in the sources examined.

2008 Other Issues

In July 2004, a Prioritising Summary was written on the use of the PoleStar intra-operative (low field) MRI for head and neck surgery. This summary was referred on the basis that Queensland Health was writing a Health Technology Assessment on all forms of intra-operative MRI. PoleStar is now distributed by Medtronic, and although 40 units are now in use worldwide, there are currently no units in use in Australia.

[6] Mean disease duration 8 years, range 1-11 years

2008 SUMMARY OF FINDINGS

Only one, good quality, study reported on the comparison of screening modalities for patients with early symptoms of RA. Two other studies were included which monitored patients with long-term disease. In all three studies it was reported that low-field MRI performed as well as high-field MRI and X-ray in the detection of bone erosions. In addition, low-field MRI was effective in detecting synovitis. Low-field MRI is cheaper to perform than high-field MRI.

2008 HEALTHPACT ACTION:

Based on the good quality evidence it would appear that low-field MRI is useful to diagnose and monitor patients with rheumatoid arthritis. Patients are not exposed to ionising radiation and can therefore be monitored closely for the effectiveness of treatment regimes. The use of low-field MRI would appear to be increasing in Australia, raising issues surrounding MBS rebates as MRI services currently attract a rebate only when conducted in accredited centres when patients are referred by a specialist. Due to access and funding issues surrounding this technology, HealthPACT recommended that it be monitored for further information in 12-months time.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level II diagnostic evidence	2
Level III-2 diagnostic evidence	1

REFERENCES:

Access Economics Pty Ltd (2005). *The economic cost of arthritis in New Zealand* Available from: http://www.arthritis.org.nz/doc-news/18.pdf

AIHW (2005). *Arthritis and musculoskeletal conditions in Australia 2005,* Australian Institute of Health and Welfare. Available from:

Ejbjerg, B. J., Narvestad, E. et al (2005). 'Optimised, low cost, low field dedicated extremity MRI is highly specific and sensitive for synovitis and bone erosions in rheumatoid arthritis wrist and finger joints: comparison with conventional high field MRI and radiography', *Ann Rheum Dis*, 64 (9), 1280-1287.

FASEB (2007). *Breakthroughs in Bioscience: Magnetic Resonance Imaging* [Internet]. Federation of American Societies for Experimental Biology. Available from: http://opa.faseb.org/pdf/mri.pdf [Accessed 28th May].

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Hori, M., Okubo, T. et al (2006). 'Line scan diffusion tensor MRI at low magnetic field strength: feasibility study of cervical spondylotic myelopathy in an early clinical stage', *J Magn Reson Imaging,* 23 (2), 183-188.

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Taouli, B., Zaim, S. et al (2004). 'Rheumatoid arthritis of the hand and wrist: comparison of three imaging techniques', *AJR Am J Roentgenol,* 182 (4), 937-943.

SEARCH CRITERIA TO BE USED:

Arthritis, Rheumatoid/complications/*diagnosis
Magnetic Resonance Imaging
Bone Diseases/diagnosis
Disease Progression
Synovitis/*diagnosis
Edema/diagnosis
Tenosynovitis/diagnosis