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Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summaries

W. Lorenz Total Temporomandibular Joint Replacement System

March 2006



ASERNIP'S

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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:

Total Temporomandibular Joint (TMJ) Replacement System (W.Lorenz Surgical Incorporated [a Biomet company], Jacksonville, FL, USA).

Purpose and Target Group:

The TMJ Replacement System is indicated for the reconstruction of the temporomandibular joint in patients where reconstruction is necessary as a result of their diagnosis (e.g. arthritic conditions, ankylosis, avascular necrosis etc.).

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

The W.Lorenz TMJ Replacement System is registered in the Australian Registry of Therapeutic Goods (ARTG number: 15695).

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Europe		✓	
Canada		✓	
South Africa		✓	

Impact Summary:***Background***

The temporomandibular joint is the diarthrosis joint connecting the lower jaw (mandible) to the temporal bone at the side of the skull. There is a TMJ on each side of the jaw, each comprised of muscles, blood supply, nerves and bones (Al-bargi *et al.* 2006). It acts as a hinge joint and in conjunction with muscles allows the jaw to open and close, move forward and backward, and side to side (Anatomica 2001). When the mouth is opened the rounded ends of the lower jaw (the condyles) slide along the socket of the temporal bone. When the

mouth is closed the condyles return to their original position. A cartilaginous disc located between the condyles and the temporal bone helps to maintain motion smooth by absorbing to the TMJ from movement such as chewing.

TMJ syndrome is a name given to a wide range of medical problems related to the jaw joint and the surrounding muscles of the jaw. Common symptoms of TMJ syndrome include pain, discomfort, clicking of the jaw, aching or tender muscles, locking or restricted joint movement, neck pain, headache and toothaches (Anatomica 2001).

The causes of TMJ syndrome can vary from trauma, disease, wear as a result of ageing, or habit. Trauma may include a hard hit to the jaw which can break the jawbone or damage the disc (Al-bargi *et al.* 2006). Diseases such as osteoarthritis and rheumatoid arthritis can also affect the TMJ and may lead to degeneration of cartilage and erode bone as well as calcification of the ligaments or fusion (ankylosis) (Anatomica 2001). Wear as a result of ageing may also lead to bone and cartilage degeneration compromising the function of the TMJ. Finally habits such as clenching and teeth grinding also cause muscle spasms and inflammatory responses. Stress has also been documented as a cause of TMJ syndrome (Al-bargi *et al.* 2006).

Clinical Need and Burden of Disease

In the United States, the TMJ Association has estimated that approximately 10 million people suffer from TMJ problems at any given time (TMJ Association 2006). A review by Baird and Rea (1998) however, reports that approximately 30 million Americans are affected by TMJ problems and that a further 1 million patients are diagnosed yearly (Baird & Rea 1998).

While the majority of TMJ problems are able to be managed through the use of non-invasive treatment there is still a proportion of patients, around 8% who require surgical intervention (Baird & Rea 1998). TMJ surgery has been associated with significant risks due to unwarranted and unsatisfactory results (Tmjoints 2006). Serious long term medical problems have also been reported by the FDA as a result of the use of certain implants (US Food and Drug Administration 2006).

Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System

The United States Food and Drug Administration (FDA) gave approval to market the TMJ Replacement System on 21 September 2005. The TMJ Replacement System has received the Conformité Européene (CE) Mark in Europe and was approved for marketing in November 23, 2000. In Canada the TMJ Replacement System has received approval from the Health Protection Branch (HPB) and was issued a medical device licence for marketing on January 14, 2004. In South Africa the device has been marketed since January 2000.

In Australia, the TMJ Replacement System has been approved by the Therapeutic Goods Administration (TGA) and is distributed by Biomet Australia Pty Ltd. (ARTG Number: 15695). Although this implant is currently available in Australia, the extent of utilisation is currently not known.

Existing Comparators

- Home Self-Care: anti-inflammatory pain medication, diet of soft foods, application of warm compresses on area of pain, mandible exercises, relaxation techniques to reduce stress.
- Splint or bite plate
- Arthrocentesis
- Arthroscopy
- Arthroplasty (open joint surgery)
- Partial joint replacement
- Total joint replacement
- Other TMJ replacement systems:
 - Christensen TMJ Prosthesis System (TMJ Implants Inc.)
 - Morgan Implant (The Temporomandibular Research Foundation)
 - Anspach Total Temporomandibular Implant (TMJ Concepts)

Estimated Cost Impact

The cost associated with the use of the Lorenz TMJ Replacement System was not revealed in our searches. The Medicare Benefits Schedule item numbers, reimbursements and number

of claims between July 2004 and June 2005 for procedures related to the treatment of TMJ disorders are outlined in Table 1.

Category	Item Number	Benefit	Number of Claims (July 2004 – June 2005)
Manipulation of temporomandibular joint.	53206	\$92.80	12
Reconstruction of glenoid fossa, zygomatic arch and temporal bone.	53209	\$1427.25	0
Arthroscopy of temporomandibular joint.	53215	\$353.70	1
Arthroscopy, removal of loose bodies, debridement or treatment of adhesions of temporomandibular joint.	53218	\$565.80	71
Arthrotomy of temporomandibular joint.	53220	\$285.25	1
Open surgical exploration of temporomandibular joint.	53221	\$754.95	4
Open surgical exploration, with condylectomy or condylotomy of temporomandibular joint.	53224	\$836.90	5
Arthrocentesis, irrigation of temporomandibular joint after insertion of 2 cannuli into the appropriate joint space(s).	53225	\$251.40	375
Synovectomy of temporomandibular joint.	53226	\$270.30	0
Open surgical exploration, with or without meniscus or capsular surgery, including meniscectomy of temporomandibular joint.	53227	\$1028.35	9
Open surgical exploration with meniscus, capsular and condylar head surgery of temporomandibular joint.	53230	\$1158.40	16
surgery of temporomandibular joint involving procedures to which 53224, 53226, 53227 and 53230 apply and involving use of tissue flaps or cartilage graft, or allograft implants.	53233	\$1301.65	47
Stabilisation of temporomandibular joint.	53236	\$407.35	2
Arthrodesis of temporomandibular joint.	53239	\$407.35	0
Application of external fixator to temporomandibular joint (s) other than for fractures treatment.	53242	\$270.30	1

Table 1. Summary of Medicare Benefits Schedule data for TMJ disorder procedures.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	1
Case series studies	1

The study included in this summary is highlighted in bold in the reference list.

Efficacy

The FDA safety and efficacy summary provided data on 224 cases (cohort unimputed = 85, cohort imputed = 119) where patients were treated with the TMJ replacement system. Primary efficacy endpoints were jaw pain intensity (as measured on a 10 cm visual analogue scale (VAS)), interference with eating (as measured on a 10cm VAS) and maximal incisal opening (MIO) from preoperative assessment to the 3 year follow-up interval. The cohort imputed group used data points obtained at the follow-up visits closest to but not after the 3

year follow-up for the analysis of the 34 patients missing at the 3 year time point. Significant improvements were observed in the cohort imputed group (n = 119) for all three primary efficacy endpoints. When 3 year follow-up and baseline values were compared, jaw pain intensity decreased by 5.69 ± 2.33 cm, interference with eating decreased by 5.42 ± 2.58 cm while MIO increased by 10.69 ± 8.22 mm. Similarly, the cohort unimputed patients achieved significant improvements in all primary efficacy endpoints as well with a 6.01 ± 2.12 cm decrease in jaw pain, 5.60 ± 2.32 cm decrease in eating interference and 10.16 ± 8.72 mm increase in MIO. In addition to this, t-test analysis revealed that the total group (n = 224) and the cohort imputed group (n = 119) achieved statistically significant ($p < 0.0001$) improvements in all three primary endpoints between baseline values and assessments at all time points from one month to three years follow-up (US Food and Drug Administration 2005).

Table 2 outlines the gradual improvement of all three primary efficacy endpoints after surgery. Patients were generally satisfied with their outcomes with 90% reporting being satisfied or better at each follow-up interval (US Food and Drug Administration 2005).

Visit (interval)	N	Jaw pain	Interference with eating	MIO
		Mean \pm SD	Mean \pm SD	Mean \pm SD
Vs 1 (baseline)	224	8.5 ± 2.3	8.5 ± 1.6	20.1 ± 10.0
Vs 3 (1 month)	293	4.6 ± 2.4	4.4 ± 2.3	24.9 ± 5.8
Vs 4 (3 months)	181	3.7 ± 2.5	3.5 ± 2.4	28.5 ± 5.8
Vs 5 (6 months)	177	3.4 ± 2.3	3.2 ± 2.4	29.4 ± 6.1
Vs 6 (1 year)	150	3.1 ± 2.4	3.0 ± 2.3	30.1 ± 5.8
Vs 7 (1.5 years)	128	3.4 ± 2.3	3.2 ± 2.5	29.6 ± 6.1
Vs8 (3 years)	85	2.8 ± 2.1	2.8 ± 2.0	29.3 ± 6.0
Vs 9 (4 years)	48	3.5 ± 2.4	3.4 ± 2.6	28.4 ± 6.6
Vs 10 (5 years)	20	4.0 ± 2.7	4.3 ± 2.3	28.9 ± 6.8
Vs 11 (6 years)	14	3.7 ± 2.1	3.2 ± 2.0	26.8 ± 5.9

Table 2: Data of all three primary efficacy endpoints at each follow-up interval (US Food and Drug Administration 2005)

A patient was considered successfully treated if no permanent joint removal was required and if the patients achieved two of the following three criterias: a) reduction of pain by 1 cm (VAS) from baseline to 3 year follow-up b) reduction of interference with eating by 1 cm (VAS) from baseline to 3 year follow-up or c) increase in MIO of 10% from baseline to 3 year follow-up. Based on these parameters, 84/85 (98.8%) patients from the cohort unimputed group and 116/119 (97.5%) patients from cohort imputed group were successfully treated.

Safety

Radiographic assessment of the implant including position of the components, heterotopic bone formation, osseous erosion and fossa resorption was carried out at each follow-up. A change in the position of three mandibular components was reported by comparing immediate postoperative radiographs to the position of components at each follow-up visit.

The comparisons revealed one component had changed position at 3 months post-implantation, while two components had changed position at the 3 year follow-up. Heterotopic bone formation was reported in a total of 15 joints (8 right and 7 left joints). The time point at which heterotopic bone formation was first observed was not reported. There were no reports of osseous erosion or fossa resorption.

Of the 224 cases, 80 of them reported a total of 121 adverse events. In total there were 15 cases (20 joints) which required removal of the implanted device as a result of an adverse event. Ten cases (11 joints) were permanent removals while 5 cases (9 joints) were non-permanent removals. The adverse events causing removal of the implants included aseptic necrosis, infection, swelling, heterotopic bone growth, dislocation and malocclusion. A total of 94 cases (42%) reported adverse events not requiring the removal of the device. There were 27 different types of adverse events reported. The three top adverse events reported were increased pain as a result of a motor vehicle accident, neuroma excision and coronoidectomy.

Wound healing at the surgical site was also assessed. All right-side surgical wounds and 98% of left-side surgical wounds had healed by the three month follow-up.

Three deaths were reported throughout the duration of the study. None were related to the use of the device.

Contraindications

The Summary of Safety and Effectiveness Data provided by the FDA as well as the manufacturer state various contraindications for the TMJ Replacement System (US Food and Drug Administration 2005, W.Lorenz Surgical 2005). These include:

- Patients with active or chronic infection
- Patients with low quality or quantity of bone to support the TMJ Replacement System
- Patients with systematic disease susceptible to infection
- Patients with extensive perforations in the mandibular fossa and/or bony deficiencies in the articular eminence or zygomatic arch potentially compromising support for the artificial fossa component of the TMJ Replacement System
- Patients with a partial TMJ reconstruction
- Patients with known allergies to any of the materials used in the components of the TMJ Replacement System
- Patients unable or unwilling to follow postoperative care procedures
- Patients that are skeletal immature
- Patients suffering severe hyper-functional habits such as teeth clenching and grinding
- Patients who have experienced a foreign body reaction to previous implants

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

No issues were identified from the retrieved literature.

Recommendation:

The only available study on the W.Lorenz TMJ Replacement System was the case series included in the FDA safety and efficacy summary. Based on the limited evidence available on this device, it is recommended that the following be conducted:

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in February 2006.

Search terms used were: ‘Temporomandibular jaw replacement’, ‘TMJ’, ‘TMJ replacement system’, ‘Temporomandibular joint replacement system’, ‘Lorenz TMJ’, and ‘TMJ implant’.

This Horizon Scanning Prioritising Summary was prepared by Mr. Luis Zamora and Mr. Irving Lee from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers’ Advisory Council (AHMAC).