



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology Prioritising Summary**

## **Biodegradable stents for coronary artery disease**

**August 2007**



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



**Royal Australasian  
College of Surgeons**

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# PRIORITISING SUMMARY

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**REGISTER ID:** S000043

**NAME OF TECHNOLOGY:** BIODEGRADABLE STENTS

**PURPOSE AND TARGET GROUP:** PATIENTS WITH CORONARY ARTERY DISEASE UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS

**STAGE OF DEVELOPMENT (IN AUSTRALIA):**

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

**AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL**

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

**INTERNATIONAL UTILISATION:**

COUNTRY	LEVEL OF USE		
	Trials underway or completed	Limited Use	Widely Diffused
Japan	✓		
United States	✓		
Germany	✓		

**IMPACT SUMMARY:**

Biodegradable stents are not available for use in Australia and are currently being trialled in various overseas centres to determine their safety and efficacy. It is likely that biodegradable stents, once proven to be effective, will have substantial impact on the Australian healthcare system. If approved in the future, these stents will be available in specialist medical centres for patients with coronary artery disease.

## BACKGROUND

Percutaneous coronary intervention (PCI) with coronary stenting is a widely utilised treatment procedure for patients with coronary artery disease. Coronary stents were developed to address the limitations of balloon angioplasty by providing scaffolding and preventing early recoil as well as late vascular remodelling (Waksman 2006). Put simply, the main functions of a coronary stent are to treat dissection and prevent restenosis. Studies have shown that coronary dissections are effectively contained by stent insertion and undergo a healing process, with the majority of coronary events occurring within the first 6 months. Similarly, restenosis has been shown to occur usually within the first 6 months. Therefore, there appears to be little benefit to have a permanent stainless steel stent in place beyond this time frame (Colombo and Karvouni 2000).

In addition to their apparent lack of function after 6 months, coronary stents are continually plagued with inherent limitations such as: stent thrombosis, which requires prolonged antiplatelet therapy; mismatch of stent to vessel size, which results in a smaller lumen after stent implantation; prevention of lumen expansion associated with late favourable remodelling; impairment of vessel geometry; and obstruction of side branches (Waksman 2006). The development of drug-eluting stents has resulted in substantial reduction of restenosis rates and the need for repeat revascularisation. However, these stents are still associated with subacute and late thrombosis which therefore necessitates prolonged antiplatelet therapy (at least 12 months) (Waksman 2006, Tamai et al. 2000). Other issues that may arise with the use of permanent stents (drug-eluting or not) is the fact that excessive use of these stents may interfere with traditional reinterventional techniques such as bypass graft surgery and may pose artefacts with modern imaging techniques such as magnetic resonance imaging (MRI) and multislice computerised tomography (MSCT) (Waksman 2006).

Considering the short-term need and the potential for long-term complications associated with permanent metallic stents, researchers have proposed that stents made of entirely biodegradable material may be an ideal alternative. Late complications associated with stent implantation, including in-stent restenosis, may be overcome with the use of biodegradable stents which dissolve to non-toxic substances after maintaining luminal integrity during the period of high-risk restenosis in the first 6 to 12 months after treatment (Commandeur et al. 2006). In addition to this, biodegradable stents can be engineered to function as a large drug reservoir, allowing for the incorporation of larger amount of drugs compared to current drug-eluting stents (Commandeur et al. 2006).

At the time of writing, several biodegradable stents have been trialled in humans. Of these is the Igaki-Tamai coronary stent, a coil stent made of poly-*l*-lactic acid (PLLA) monofilament in a zigzag helical design (Tamai et al. 2000). To date, the Igaki-Tamai stent is the only biodegradable polymeric coronary stent trialled in humans with published peer-reviewed data. In addition to biodegradable polymeric stents, researchers have developed biodegradable metallic stents as well. At the time of writing, two biodegradable metal alloys have been proposed for this application; iron and magnesium (Waksman 2006). However, only magnesium alloy stents have been trialled at the time of writing.

## **CLINICAL NEED AND BURDEN OF DISEASE**

Coronary artery disease (a.k.a. coronary heart disease) is the most common form of heart disease in Australia. The 2004-2005 National Health Survey reported that 1.7% of Australians surveyed admitted to having manifestations of coronary artery disease. This corresponds to approximately 334,500 Australians affected by this disease (Australian Institute of Health and Welfare 2006).

In 2003, approximately 49,800 coronary artery disease events occurred in Australia among 40 to 90 year olds. Less than 50% of these events were fatal (21,480 fatalities) and 86% of these deaths occurred outside of a hospital (AIHW 2006). Coronary artery disease has been determined as the largest single cause of death in Australia in 2004, accounting for 24,576 deaths, which equates to 19% of all deaths and 51% of cardiovascular deaths. Research has shown that the number of coronary artery disease deaths increases greatly with age; with approximately 73% of all coronary artery disease deaths occurring among those aged 75 years or over (Australian Institute of Health and Welfare 2006).

In addition to this, coronary artery disease is one of the major causes of disability in Australia. The 2003 Survey of Disability, Aging and Carers revealed that 1.5% of respondents reported one or more disabling conditions associated with coronary heart disease; which corresponds to approximately 303,500 Australians. The survey also reported that 49% of these required help or had difficulties with self-care, mobility or communication (Australian Institute of Health and Welfare 2006).

## **DIFFUSION**

The Australian Institute of Health and Welfare states that coronary revascularisation procedures (percutaneous coronary interventions and coronary artery bypass grafting) are very common; and are performed at a rate of over 100 per day, totalling 38,901 procedures in 2000. In 2000, percutaneous coronary intervention procedures accounted for 56% (21,784 procedures) of revascularisation procedures (Australian Institute of Health and Welfare 2000).

Considering the fact that percutaneous coronary interventions with stent implantation is commonly conducted in Australia, it is likely that biodegradable stents will be embraced with enthusiasm if they are proven to have substantial advantages compared to current bare-metal and drug-eluting stents. Only a handful of companies have developed/ been developing biodegradable coronary stents; Table 1 lists the biodegradable stents currently being researched or trialled:

**Table 1: List of biodegradable stents currently being trialled / developed for coronary artery disease**

Company	Stent name	Drug/Process	Trial
Abbott Vascular	BVS	Everolimus, biodegradable polylactic acid (PLA)	ABSORB first-in-man clinical trial (began March 2006, results pending)
Bioabsorbable Therapeutics Inc.	IDEAL	Salicylic acid, sirolimus, biodegradable polyanhydride ester (PAE)	Preclinical research
Biotronik	Absorbable Metal Stent (AMS)	Magnesium alloy	PROGRESS trial
Endovasc-TissueGen Research Sponsors (joint venture)	(Undisclosed)	Prostglandin E-1, biodegradable polymer stent	In development
N/A	Igaki-Tamai stent	Biodegradable polymer stent	Long-term trial in progress
REVA Medical	REVA Medical Resorbable Stent	Paclitaxel, biodegradable tyrosine-derived polycarbonate polymer	RESORB (first human trials to begin early 2007)

MedMarket Diligence (2007)

## COMPARATORS

- Conventional coronary artery bypass surgery
- Percutaneous coronary artery bypass surgery (da Vinci surgical system)
- Bare metal stents
- Drug-eluting stents

## SAFETY AND EFFECTIVENESS ISSUES

Studies on biodegradable coronary stents were retrieved for inclusion in this summary. All peer-reviewed case series studies were included while case reports were excluded from assessment.

### a) Safety

#### *Igaki-Tamai stent*

Tamai et al. (2000) were the first investigators to report initial and 6-month results for the Igaki-Tamai stent after implantation in 15 patients with coronary artery stenosis; a total of 25 stents were implanted in 19 lesions during 17 procedures. There were no incidences of stent thrombosis or major cardiac events (death, Q-wave myocardial infarction, and repeat percutaneous transluminal coronary angioplasty or coronary artery bypass grafting) in all 15 patients within the first 30 days after implantation. Two patients experienced mild creatine kinase elevation (greater than 2 times but less than 3 times the upper normal limit) after debulking procedures. At 6-months follow-up, the investigators reported no deaths or incidences of myocardial infarctions in any of the 15 patients. None

of the patients required coronary artery bypass grafting; however one patient required repeat percutaneous transluminal coronary angioplasty for re-dilation of 2 lesions. No incidence of stent thrombosis was observed in this cohort under the aspirin and ticlopidine regimen (Tamai et al. 2002).

Tsuji et al. (2001) published one year follow-up results of the Igaki-Tamai stent in 50 patients with 63 lesions and reported that subacute thromboses occurred in one patient (2%) 5 days after stenting due to inadequate heparinisation because of gastrorrhagia. There were no other cases of myocardial infarction, coronary artery bypass grafting, or death within the follow-up period of 12 months (Tsuji et al. 2001).

One of the concerns related to the use of the Igaki-Tamai stent is the fact that heat (70°C within the delivery balloon) is required for rapid expansion the stent for implantation. Previous studies have shown that mild short-term temperature elevation (65°C to 70°C for several seconds) can result in necrosis of the arterial wall with subsequent proliferation of smooth muscle cells (Colombo and Karvouni 2000), therefore causing re-stenosis. However, preliminary studies (Tamai et al. 2000, Tsuji et al. 2001) have not reported any evidence that supports this.

#### *Magnesium alloy stents*

Studies on biodegradable magnesium alloy stents, which contain small amounts of aluminium, manganese, zinc, lithium and rare earth elements, have been reported in several preclinical and peripheral vascular studies (Waksman 2006); however studies on its application in coronary arteries have so far been limited to one multicentre trial (Erbel et al. 2007) and case reports (Bose et al. 2006). The prospective, non-randomised, multicentre trial (PROGRESS trial) was designed to evaluate the safety and efficacy of magnesium alloy stents (Biotronik Absorbable Metallic Stents, The Netherlands) in 63 patients with coronary artery disease and is the largest study to date on magnesium alloy stents. At 4-months post-stenting, all patients underwent a coronary angiogram and intravascular ultrasound examination. Clinical follow-up was repeated at 6 months and 12 months. The investigators noted no deaths, cardiac deaths, fatal or non-fatal myocardial infarctions, or stent thrombosis during hospital stay up to 12 months post-stenting. At 12 months, a total of 16 patients (26.7%) experienced major adverse cardiac events<sup>1</sup> (MACE); with a substantial proportion (15 patients, 23.8%) occurring within 4 months post-stenting. Target lesion revascularisation and target vessel revascularisation was necessary in 27 patients (45%)

The first coronary implantation of an absorbable magnesium alloy stent (The Magic stent, Biotronik, Switzerland) was conducted in Essen, Germany in 2005. Intravascular ultrasound (IVUS) revealed that the elastic stent recoil was 6% to 7%, but no other safety parameters were reported (Bose et al. 2006).

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<sup>1</sup> MACE: defined as cardiac death, Q-wave myocardial infarction or clinically driven target lesion revascularisation.

## b) Effectiveness

### *Igaki-Tamai stent*

Before stent implantation, Tamai et al. (2000) stated that the lesions were dilated by optimally size balloons or by directional atherectomy. All stents were successfully delivered in all 15 patients, and angiographic success<sup>2</sup> was achieved in all procedures. Quantitative coronary angiography (QCA) (Table 1) revealed that the percent diameter stenosis decreased from 64% before stenting to 12% immediately after stenting; while minimal lumen diameter (MLD) increased from 1.02mm before stenting to 2.59mm after stenting. Percentage acute stent recoil<sup>3</sup> was  $22 \pm 7\%$ .

**Table 2: Quantitative coronary angiography analysis of patients treated with the Igaki-Tamai stent**

	Before stenting	After stenting	1 day after stenting	3-month follow-up	6-month follow-up
<b>Lesion number</b>	19	19	19	19	18
<b>Reference vessel diameter (mm)</b>	2.85±0.34	2.95±0.35	3.00±0.40	2.75±0.49	2.69±0.49
<b>MLD (mm)</b>	1.02±0.36	2.59±0.35	2.58±0.32	1.88±0.59	1.84±0.66
<b>Percent diameter stenosis (%)</b>	64±11	12±8	13±11	33±14	33±18
<b>Loss index</b>				0.44±0.30	0.48±0.32

MLD: Minimal lumen diameter  
Loss index: late loss/initial gain

Tamai et al. (2000)

At one day post-stenting, percent diameter stenosis was 13% and MLD was 2.58mm, no different to the measurements immediately after stenting. Follow-up coronary angiograms suitable for quantitative coronary angiography analysis were obtained in all 15 patients at 6-months. The investigators noted that mean MLD had decreased from  $2.58 \pm 0.32$ mm (1-day post-stenting) to  $1.88 \pm 0.59$  at 3-months and  $1.84 \pm 0.66$  at 6-months. Meanwhile percent diameter stenosis had increased from  $13 \pm 11\%$  (1-day post-stenting) to  $33 \pm 14\%$  at 3-months and  $33 \pm 18\%$  at 6-months (Table 1). The angiographic restenosis rate per lesion was 10.5% (2/19 lesions) while angiographic restenosis rate per patient was 6.7% (1/15 patients) at 3-months. At 6-months post-stenting, the angiographic restenosis rate and the target lesion revascularisation rate per lesion were 10.5% (2/19 lesions), while the restenosis rate per patient was 6.7% (1/15 patients).

<sup>2</sup> Procedure was considered successful if residual stenosis <50% and Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow was achieved.

<sup>3</sup> Percentage of acute stent recoil: (max inflated balloon diameter-final MLD)/maximal inflated balloon diameter x 100.

**Table 3: Quantitative intravascular ultrasound (IVUS) analysis of patients treated with the Igaki-Tamai stent**

	After stenting	1 day after stenting	3-month follow-up	6-month follow-up
Lesion number	19	19	18	18
Stent CSA (mm <sup>2</sup> )	7.42±1.51	7.37±1.44	8.18±2.42*	8.13±2.52*
Neointimal area (mm <sup>2</sup> )	-	-	2.51±0.94	2.50±0.65
Lumen CSA (mm <sup>2</sup> )	7.42±1.51	7.37±1.44	5.67±2.42†	5.64±2.70‡

CSA: Cross sectional area

\*p < 0.1 vs after stenting; †p < 0.005 vs after stenting; ‡p < 0.001 vs after stenting.

At 3-months, the IVUS record for one non-restenotic lesion was missing and was not analysed.

At 6-months, one lesion was not analysed as it required repeat angioplasty.

Tamai et al. (2000)

Quantitative IVUS analysis of the same cohort revealed no significant difference in stent cross sectional area (CSA) immediately after stenting and at 1-day post-stenting, corresponding to MLD measurements obtained via QCA. Mean stent CSA tended to be larger at 3- and 6-months compared stent CSA immediately after stenting (Table 2). Mild neointimal hyperplasia was detected in the arteries at 3-month follow-up but did not increase at 6-months follow-up; meanwhile lumen CSA remained similar between 3- and 6-months as well. This indicates that the Igaki-Tamai stent does not result in pronounced intimal hyperplasia and according to the investigators, it appears to be comparable to bare-metal stents. The results showed an increase of stent CSA from 7.42mm<sup>2</sup> at baseline to 8.18mm<sup>2</sup> at 3-months; implying that vascular remodelling may have occurred at the stented site (Table 2). The investigators noted that this expansion of stent CSA was associated with a decrease in lumen CSA (Table 2), no further stent expansion was observed beyond the 3-month follow-up. One of the major concerns with biodegradable stents is whether stent degradation occurs within a reasonable time frame, due to the fact that stents must continue to provide scaffolding support for > 6 months to overcome late vessel remodelling. IVUS analysis at follow-up revealed that the struts of the Igaki-Tamai stent were still present at 6 months indicating that the stent should be capable of providing support up to 6 months post-implantation (Tamai et al. 2000).

Tsuji et al. (2001) reported that QCA of 50 patients (63 lesions) at 3, 6 and 12 months revealed percent diameter stenosis of 12 ± 8 %, 38 ± 23%, and 33 ± 23%, respectively. Restenosis rates were 21% (12/58 lesions) at 6 months and 19% (7/36 lesions) at 12 months; while target lesion revascularisation rates was 12% (7/58 lesions) at 6-months and 17% (6/36 lesions) at 12 months (Tsuji et al. 2001). However, this study experienced substantial patient attrition at 12-months follow-up and the results should be interpreted with caution. In comparison to Tamai et al. (2000), the 6-month restenosis rates were substantially higher (21% vs. 10.5%) but lesion revascularisation rates were similar (12% vs. 10.5%).

Both studies demonstrated feasibility and safety in deployment of the Igaki-Tamai stent, and found acceptable efficacy in patients treated. However, it should be noted that both studies had major limitations in identifying signs of biodegradation and both are limited

to a relatively small patient cohort with substantial loss of follow-up in one study (Tsuji et al. 2001).

### *Magnesium alloy stents*

The PROGRESS trial reported significantly increased in-segment minimal luminal diameter ( $p < 0.0001$ ) and significantly decreased in-segment diameter stenosis ( $p < 0.0001$ ) immediately after stenting. Compared to QCA data immediately after stenting, 4-months follow-up results revealed that in-segment minimal luminal diameter decreased significantly ( $2.47 \pm 0.38\%$  [ $n = 60$ ] to  $1.38 \pm 0.51\%$  [ $n = 59$ ];  $p < 0.00001$ ) while in-segment diameter stenosis increased significantly ( $20.50 \pm 7.50\%$  [ $n = 60$ ] to  $49.66 \pm 16.25\%$  [ $n = 59$ ];  $p < 0.00001$ ). Significant decreases were noted for proximal margin minimal luminal diameter ( $2.6 \pm 0.47\%$  [ $n = 60$ ] to  $2.23 \pm 0.65\%$  [ $n = 59$ ];  $p < 0.00001$ ), in-segment minimal lumen diameter ( $2.18 \pm 0.38\%$  [ $n = 60$ ] to  $1.34 \pm 0.49\%$  [ $n = 59$ ];  $p < 0.00001$ ), distal margin minimal luminal diameter ( $2.28 \pm 0.44\%$  [ $n = 60$ ] to  $2.07 \pm 0.56\%$  [ $n = 59$ ];  $p = 0.00203$ ); while a significant increase was observed for proximal margin diameter stenosis ( $11.87 \pm 8.47\%$  [ $n = 60$ ] to  $18.25 \pm 19.09\%$  [ $n = 59$ ];  $p = 0.00114$ ) and in-stent diameter stenosis ( $12.65 \pm 5.63\%$  [ $n = 60$ ] to  $48.37 \pm 17.00\%$  [ $n = 59$ ];  $p = 0.00001$ ). Vessel reference diameter remained unchanged pre-stenting to 4 months post-stenting. The in-segment and in-stent restenosis rates at 4-months were  $47.5 \pm 59\%$ . Overall, the study reported that diameter stenosis was reduced from  $61.5 \pm 13.1\%$  to  $12.6 \pm 5.6\%$  with an acute gain of  $1.41 \pm 0.46\text{mm}$  and in-stent late loss of  $1.08 \pm 0.49\text{mm}$ . With regards to the biodegradability of the stent, the investigators stated that no residual metal was detected by IVUS; indicating complete degradation and that in-stent thrombosis would be unlikely at later stages (Erbel et al. 2007).

The results of the PROGRESS trial suggest that the biodegradable magnesium stent is capable of achieving immediate angiographic results which appear to be similar to that of bare-metal stents while achieving complete biodegradation within 4 months.

### **COST IMPACT**

The cost of biodegradable coronary stents is currently unknown. However, there is a possibility that the first generation of commercial biodegradable stents will cost substantially more than drug-eluting stents.

The Medicare Benefits Schedule reimbursement fees for procedures relating to the implantation of coronary stents are listed in Table 1.

**Table 5: Medical Benefits Schedule of procedure related to the treatment of coronary artery disease and stenting**

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Transluminal stent insertion of 1 or more stents (not drug-eluting) with or without associated balloon dilatation for 1 carotid artery	35307	\$990.75	187
Transluminal insertion of stent or stents into one occlusion site including associated balloon dilatation for coronary artery, percutaneous or by open exposure.	38306	\$673.70	21019
Percutaneous transluminal rotational atherectomy of 1 coronary artery, including balloon angioplasty with insertion of 1 or more stents.	38312	\$1000.65	84
Percutaneous transluminal rotational atherectomy of more than 1 coronary artery, including balloon angioplasty, with insertion of 1 or more stents.	38318	\$1401.75	21

(Department of Health and Aging 2007)

### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified from the retrieved material.

### **OTHER ISSUES**

It should be noted that the Biotronik Absorbable Metal Stent is completely radiolucent and cannot be visualised with X-ray due to its >90% magnesium composition. Therefore evaluation of post-interventional stent expansion would require the use of intravascular ultrasound. Eggebrecht et al. (2005) highlighted that due to the fact that the Biotronik stent does not exert metallic artefacts, it has potential for non-invasive follow-up with magnetic resonance imaging.

### **SUMMARY OF FINDINGS**

The evidence available presents short-term results on two biodegradable stents (the Igaki-Tamai stent and the Biotronik Absorbable Metallic Stent) and suggests that both stents are capable of achieving acceptable efficacy. However, both stents are still in the early stages of clinical trials and long-term comparative results to bare metal stents are required before any conclusions can be made with regards to their efficacy and safety. Further studies are also required to determine the 'best' degradation duration, to demonstrate clinical efficacy, ensure that the use of these stents result in substantial reduction in stent thrombosis rates compared to bare metal stents and establish long-term safety.

## HEALTHPACT ACTION:

Considering the potential of rapid adoption within the healthcare system, biodegradable stents will be monitored for 12 months as a bid to retrieve long-term safety and efficacy data.

## NUMBER OF STUDIES INCLUDED

Total number of studies        3  
Level IV intervention evidence

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**SEARCH CRITERIA TO BE USED:**

Coronary Restenosis/prevention and control\*  
Coronary Stenosis  
Coronary Restenosis  
Stents\*  
Biodegrad\* stent  
Absorbable stent  
Igaki Tamai stent  
Magnesium stent