Innovations of health services and economic evaluation of bone-anchored prosthesis using osseointegration: the Queensland Artificial Limb Service’s experience

Evidence for a cost-effective provision of bone-anchored prostheses from a governmental perspective

Queensland Government
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The proposal that John Vasil and Debra Berg submitted to me three years ago was exciting: their passion about the new way to attach an artificial limb called osseointegration was contagious!

As a doctor with interest in marriage between new technology and precision medicine, I am particularly fascinated by the current developments in enabling technologies such as endo-exoskeleton and osseointegration alike. The opportunity to improve the life of patients suffering limb loss using the revolutionary treatment was promising.

As an administrator, I am also a strong advocate for digital medical records. The prospect of integrated electronic financial and medical records to support evidence of best possible care was also thrilling.

I am particularly pleased that their ground-breaking research is coming to fruition. Indeed, I am delighted to share with you, health care administrators, an overview of their substantial findings in health service and economic evaluation specific to the provision of bone-anchored prostheses. A wealth of further in-depth information can be found in the several scientific articles their team has already published in top-ranked journals.

This report is both enjoyable and informative. I am certain that the rapid translation of this evidence into practice will ultimately improve reliability of many healthcare organisations in increasing quality of life of individuals living with an artificial limb.

Dr Richard Ashby
Chief Executive of eHealth Queensland and CIO of Queensland Health

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As a doctor with interest in marriage between new technology and precision medicine, I am particularly fascinated by the current developments in enabling technologies such as endo-exoskeleton and osseointegration alike. The opportunity to improve the life of patients suffering limb loss using the revolutionary treatment was promising.

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John Vasil
Director of Medical Aids Subsidy Scheme - Queensland Health

As leader of Medical Aids Subsidy Scheme and Queensland Artificial Limb Service, we are constantly investigating opportunities to support new assistive technologies that can improve the life of our consumers with a disability.

Debra Berg and I have been monitoring the amazing developments made by osseointegration for prosthesis in Australia and overseas for the last decade. Consequently, it was no surprise when this surgical procedure become increasingly in demand by our consumers with lower limb loss a few years ago, particularly because of climatic challenges experienced in Queensland.

As administrators, we also take pride in making sure that our critical initiatives, such as developing reimbursement policy, are based on evidence.

Consequently, we initiated three years ago to put together a team of highly reputable researchers to provide necessary evidence to create not only a fair and equitable procedure but also to produce the first economic evaluation for the provision of bone-anchored prostheses from a governmental perspective.

We are thrilled to share with you some of the most valuable lessons we have learnt during the course of this scientific journey. Indeed, we hope this summary will guide your respective endeavors toward the creation of evidence supporting the provision of ever improving bone-anchored prostheses for individual with limb loss.
CONTRIBUTOR AND QALS JURISDICTION

AUTHORS

Debra Berg
Manager of Queensland Artificial Limb Service – Queensland Health

Mrs Debra Berg has over 28 years’ experience in Queensland services, including 15 years in delivery of artificial limbs. She has been a strong advocate for bone-anchored prostheses in Australia for over a decade.

Dr Laurent Frossard (PhD)
Adjunct Professor at Queensland University of Technology and University of the Sunshine Coast, Chief Scientist Officer at YourResearchProject.

Dr Laurent Frossard has over 20 years’ experience in academia and industry in Australia, North America and Europe. He is internationally recognized as an independent expert in clinical outcomes of individuals fitted with socket-suspended and bone-anchored prostheses.

Dr Brendan Burkett AOM (PhD, MEng, FIEAust)
Professor of Sport Science at the University of the Sunshine Coast

Professor Brendan Burkett has over 30 years’ of industry experience in professional engineering and in academia at the University of the Sunshine Coast. He was the first individual in Australia fitted with a bone-anchored prosthesis using a press-fit osseointegrated fixation.

CONTRIBUTORS

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The design of artificial limbs for persons with an amputation has continuously improved over the last decade. Nonetheless, there is still a large portion of individuals who are non-prosthetic users or facing substantial challenges when using a prosthesis.

The conventional way to attach a prosthesis to the body is to use a plastic shell, called a socket, enveloping the residual limb. Unfortunately, this prosthetic attachment presents a number of shortcomings, mainly due to the friction within the socket regularly causing damage to the skin. Altogether, these issues limit mobility and ultimately reduce significantly the quality of life of a typical prosthetic users.

Most of these functional issues can be overcome by ground-breaking surgical procedures. A rod of bio-compatible material, called osseointegrated fixation, can be inserted into the residual bone such as the femur and enable external attachment of a prosthesis.

These bone-anchored prostheses present major clinical and prosthetic benefits with acceptable risks of infection, leading to a significant improvement in quality of life, particularly for young, active, and nonvascular individuals with above-the-knee amputation.

Benefits and opportunities for bone-anchored prostheses have been well echoed in social media worldwide generating an unprecedented high demand from groups of interests.

Consequently, policy decision makers including health care managers are under substantial pressure to support the provision of bone-anchored prostheses, while responsibly allocating scarce resources within health care systems.

In principle, bone-anchored prostheses could reduce some prosthetic, medical and financial burdens for health service administrators by reducing the treatment of skin-socket interface problems over a user’s lifespan. However, little evidence is currently available to support this claim.

Consequently, policy decision makers are left facing a series of challenges while addressing burning questions: Is the fair and equitable provision of bone-anchored prostheses required to have a specific procedure? What are the actual costs of the provision of bone-anchored prostheses? What is the cost-effectiveness of bone-anchored prostheses compared to conventional socket-suspended prostheses?

In 2011, the Queensland Artificial Limb Service (QALS), an Australian State Government public health organization initiated a research project to address these issues and provide strong evidence supporting the provision of bone-anchored prostheses.

The purpose of this report is to share the knowledge gained by QALS during this project and to present subsequent health services innovations in the design of the policy, the assessment of the actual costs and production of cost-effectiveness associated with the provision of bone-anchored prostheses.

The outcomes of this first economic evaluation from an Australian State Government public health prosthetic care and funding scheme’s perspective, indicates that the provision of bone-anchored prostheses can be supported by fair, equitable and affordable policy while being cost-effective. Thereby indicating, the new attachment relying on osseointegrated fixation is an acceptable alternative to conventional intervention at least from a public health prosthetic care and funding perspective.

The experience reported here provides a working template for the development of economic evaluations to stakeholders responsible for policies around the care of individuals fitted with bone-anchored prostheses worldwide.
BENEFITS AND OPPORTUNITIES FOR BONE-ANCHORED PROSTHESES HAVE BEEN WELL ECHOED IN SOCIAL MEDIA WORLDWIDE
STUDY DESIGN
The contributions presented in this report emerged from a three-year project of research using a range of approaches including literature review, action research, observational study such as typical routine-data-based study at an individual level commonly applied in epidemiology, health services and economic evaluations.

PERSPECTIVE
This study was conducted from a governmental health care perspective, namely the Queensland Health and the Queensland Artificial Limb Service’s perspective.

RESEARCH TEAM
The steering committee of this project led by the Queensland Artificial Limb Service’s management team consulted with key stakeholders including two administrators, three researchers, one health economist, three prosthetists, two multidisciplinary clinical teams as well as one consumer.

PARTICIPANTS
This project involved the first 18 Queensland-based consumers with transfemoral amputation treated with osseointegration fixation and fitted with bone-anchored prosthesis between January 2011 and June 2016.

ETHICS
The study followed ethical guidelines from the Queensland Health’s Health Innovation, Investment and Research Office (HIIRO) responsible for consultation, development and review of State-wide research ethics and research governance policies.

DATA
Typical costs and individual historical costs were extracted from the Queensland Artificial Limb Service’s form regulatory documentation and financial system while utility information was extracted from the literature, respectively.

Both costs and utility data were imported into a specifically designed database enable to compile and report all key results required to perform a state-of-the-art health services and economic evaluation research.
THE STUDY FOLLOWED ETHICAL GUIDELINES FROM THE QUEENSLAND HEALTH’S HEALTH INNOVATION, INVESTMENT AND RESEARCH OFFICE
DESCRIPTION OF QALS

<table>
<thead>
<tr>
<th>Location</th>
<th>• Brisbane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Relates to the Medical Aids Subsidy Scheme, Metro South Health and ultimately the Queensland Government Minister of Health</td>
</tr>
<tr>
<td>State organisation</td>
<td>Health and ultimately the Queensland Government Minister of Health</td>
</tr>
<tr>
<td>Role</td>
<td>Provide prosthetic services (e.g., artificial limbs) to eligible residents of Queensland, under the State Government’s</td>
</tr>
<tr>
<td>Yearly budget</td>
<td>$5.4M</td>
</tr>
<tr>
<td>Number of consumers registered</td>
<td>Over 7,000</td>
</tr>
<tr>
<td>Number of active consumers per year</td>
<td>Over 3,000</td>
</tr>
<tr>
<td>Number of active consumers with transfemoral amputation</td>
<td>Over 600 (20%)</td>
</tr>
<tr>
<td>Number of prosthetic service providers</td>
<td>6 to 10</td>
</tr>
</tbody>
</table>

BRISBANE

DESCRIPTOR INFORMATION

GEOGRAPHICAL INFORMATION ABOUT STATE OF QUEENSLAND

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital city</td>
<td>Brisbane</td>
</tr>
<tr>
<td>Population</td>
<td>4.7 million</td>
</tr>
<tr>
<td>Size</td>
<td>1.8 million km²</td>
</tr>
<tr>
<td>Average temperature</td>
<td>Summer: 35C - 21C, Winter: 22C - 10C</td>
</tr>
<tr>
<td>Average humidity</td>
<td>Summer: 50%, Winter: 65% - 75%,</td>
</tr>
</tbody>
</table>

DRIVERS

THE TOP DRIVERS FOR QALS TO INNOVATE

<table>
<thead>
<tr>
<th>Driver</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Search for alternative prosthetic attachment as Queensland’s heat and humidity make socket-suspended prostheses difficult to use</td>
<td></td>
</tr>
<tr>
<td>Face immediate and projected influx of Queensland consumers that is highest worldwide</td>
<td></td>
</tr>
<tr>
<td>Need to establish robust as well as fair and equitable procedure to provide bone-anchored prostheses</td>
<td></td>
</tr>
<tr>
<td>Need to determine cost-effectiveness of bone-anchored compared to socket-suspended prostheses to prepare budget</td>
<td></td>
</tr>
</tbody>
</table>
OUTCOMES

- The fair and equitable provision of bone-anchored prostheses can be achieved based on 7 processes involving fixed expenses during the treatment and 5 processes regulating ongoing prosthetic care expenses.

- The policy for the provision of bone-anchored prostheses can cost up to AUD$3,300 corresponding 22 hours of prosthetist’s labour per consumer.

### COSTS OF PROSTHETIST’S LABOUR PER PHASES OF TREATMENT

<table>
<thead>
<tr>
<th>REHABILITATION PHASES</th>
<th>HOURS</th>
<th>COSTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative</td>
<td>2.5</td>
<td>$375</td>
</tr>
<tr>
<td>Surgery</td>
<td>2.5</td>
<td>$375</td>
</tr>
<tr>
<td>Light limb</td>
<td>6.5</td>
<td>$975</td>
</tr>
<tr>
<td>Definitive limb</td>
<td>10.5</td>
<td>$1575</td>
</tr>
</tbody>
</table>

### COSTS OF PROSTHETIST’S LABOUR PER TASKS

<table>
<thead>
<tr>
<th>TASKS</th>
<th>HOURS</th>
<th>COSTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation</td>
<td>4</td>
<td>$600</td>
</tr>
<tr>
<td>Evaluation</td>
<td>2</td>
<td>$300</td>
</tr>
<tr>
<td>Fitting</td>
<td>14</td>
<td>$2100</td>
</tr>
<tr>
<td>Reporting</td>
<td>2</td>
<td>$300</td>
</tr>
</tbody>
</table>
LEssonS LEARNT

- The procedure required adjustments related to the typical scope of practice of prosthetists, funding of prosthetic limbs during rehabilitation, and allocation of microprocessor-controlled prosthetic knees.

- The obstacles encountered during the development of the policy were 7 (41%) and 10 (59%) within or outside governmental control, respectively.

- Approximately, 17 (89%) of the facilitators of the development of the policy were within governmental control (e.g. adapting existing processes).

INITIAL OBSTACLES

- Estimate of prosthetist’s labour for specific bone-anchored prosthetic care
- Review of paradigm for allocation of advanced prosthetic knee units
- Absence of procedures for preoperative, surgery and post-operative care

ONGOING OBSTACLES

- Slight broadening of a prosthetist’s role as case manager
- Standardization of a ‘passport of service’
- Continual evolutions of surgical procedures

KNOW FACILITATORS

- Engage early with stakeholders, particularly prosthetists
- Create of ‘passport of service’
- Create database to monitor individual and overall costs

SUGGESTED FACILITATORS

- Approve reimbursement before most expensive items
- Set processes to assess benefits of treatment
- Monitor national and international developments in osseointegration

REFERENCE


LINKS

http://rdcu.be/s99d
https://eprints.qut.edu.au/107652/1/Art-0ALS-Policy%20QLD%20experience-ePrint-03.pdf
COST COMPARISON

INNOVATION 2: COST-COMPARISON OF BONE-ANCHORED AND SOCKET-SUSPENDED PROSTHESES

OUTCOMES

• The provision of a bone-anchored prosthesis costs 18% and 79% less than typical socket-suspended prosthesis for the prosthetist labor and attachment costs, respectively.

• The provision of a “budget” bone-anchored prosthesis to the most functional consumers (K4) reduced cost by AUD$7,000 compared with socket-suspended prosthesis.

Differences in total costs between provision of “budget” bone-anchored and socket-suspended prosthesis by activity level.

<table>
<thead>
<tr>
<th>Activity Level</th>
<th>Cost Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (K1)</td>
<td>52%</td>
</tr>
<tr>
<td>Moderate (K2)</td>
<td>23%</td>
</tr>
<tr>
<td>High (K3)</td>
<td>4%</td>
</tr>
<tr>
<td>Intense (K4)</td>
<td>-12%</td>
</tr>
</tbody>
</table>

0
COST-EFFECTIVENESS

INNOVATION 3: COST-EFFECTIVENESS OF BONE-ANCHORED PROSTHESES

OUTCOMES

- The cost for the provision of a bone-anchored prosthesis is about 20% more than a socket-suspended prosthesis, which can be offset by an increase of 18% in quality-adjusted life year.
- The provision of a bone-anchored prosthesis was cost-saving and cost-effective for 19% and 88% of the participants, respectively.

REFERENCE


LINKS

http://journals.lww.com/jpojournal/Abstract/publishahead/Cost_Comparison_of_Socket_Suspended_and_99964.aspx


LESSONS LEARNT

- Suppliers of conventional prosthetic components can strongly impact the overall costs for the provision of bone-anchored prostheses.
- Manufacturers of osseointegrated fixation could play a decisive role given the cost of specific parts (e.g., connectors, protective devices).

COST-EFFECTIVENESS

INNOVATION 3: COST-EFFECTIVENESS OF BONE-ANCHORED PROSTHESES

OUTCOMES

Cost-utility analysis for provision of bone-anchored prosthesis with quadrant more costly and more effective (1), more costly and less effective (2), less costly and less effective (3), less costly and more effective (4) than socket-suspended prosthesis.
COST-EFFECTIVENESS

LESSONS LEARNT

OUTCOMES

• The incremental cost-effectiveness ratio for the provision of a bone-anchored prosthesis can be AUD$17,000 per quality-adjusted life year.

• The incremental cost-effectiveness ratio can be significantly below the commonly accepted cost-effectiveness threshold of $40,000 to $70,000 per quality adjusted life year as used by national health technology evaluation groups.

REFERENCE


LINKS

http://journals.sagepub.com/doi/10.1177/0309364617740239

LIST OF PUBLICATIONS AND PRESENTATIONS

PUBLICATIONS

   Link to PDF directly: https://eprints.qut.edu.au/107652/1/Art-QALS-Policy%20QLD%20experience-ePrint-03.pdf


   Link to PDF directly: https://eprints.qut.edu.au/114520/1/Art-QALS-Cost%20Effectiveness-ePrint-06.pdf

PRESENTATIONS

   ePrint: http://eprints.qut.edu.au/105589/

   ePrint: https://eprints.qut.edu.au/108850/

   ePrint: http://eprints.qut.edu.au/82497/

   ePrint: http://eprints.qut.edu.au/87958/

5. Burkett B, Frossard L, Berg D, Formosa D. The cost and time effectiveness of osseointegration compared to the traditional socket prosthesis. University of the Sunshine Coast - University Research Week. 2014. Maroochydore, Australia. p 27
   ePrint: http://eprints.qut.edu.au/84787

   ePrint: https://eprints.qut.edu.au/112206/

LINKS
