Development of a procedure for the government provision of bone-anchored prosthesis using osseointegration in Australia

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Abstract

Background. Governmental organizations are facing challenges in adjusting procedures providing equitable assistance to consumers with amputation choosing newly available osseointegrated fixations for bone-anchored prostheses over socket-suspended prostheses.

Objectives. The objectives were (1) to present a procedure focusing on tasks, documents and costs of prosthetic care, and (2) to share observed obstacles and facilitators to implementation.

Methods. This research aiming at developing a governmental procedure for the provision of bone-anchored prostheses was designed as an action-research study. A total of 18 individuals with transfemoral amputation solely funded by a Queensland State organization were considered.

Results. The procedure developed between 01/2011 and 06/2015 included seven processes involving fixed expenses during the treatment and five processes regulating ongoing prosthetic care expenses. Prosthetic care required 22 hours of labor corresponding to AUD$3,300 per patient during rehabilitation. Prosthetists spend 64% and 36% of their time focusing on prosthetic care and other activities, respectively. The procedure required adjustments related to scope of practice of prosthetists, funding of prosthetic limbs during rehabilitation and allocation of microprocessor-controlled prosthetic knees. Approximately 41% (7) and 59% (10) of the obstacles were within (e.g., streamlining systematic processes, sustaining evaluation of this complex procedure) or outside (e.g., early and consistent consultations of stakeholders, lack of a definitive rehabilitation program) governmental control, respectively. Approximately, 89% (17) of the facilitators were within governmental control (e.g., adapting existing processes).

Conclusion. This study provides a working plan to stakeholders developing and implementing policies around care of individuals choosing osseointegration for bone-anchored prostheses.

Key Points for Decision Makers

- The demand from prosthetic care providers and policy-makers for an in-depth presentation on an implementable procedure for the provision of bone-anchored prostheses is yet to be addressed.
- A procedure for provision of bone-anchored prostheses could include seven processes involving fixed expenses during the treatment and five processes regulating ongoing prosthetic care expenses.
- A total of 22 hours of prosthetist’s labor, corresponding to $3,300 was deemed sufficient to provide a bone-anchored prosthesis to an individual with a transfemoral amputation during the rehabilitation program.

Keywords

Amputation; Artificial limb; Bone-anchored prosthesis; Osseointegrated implants; Osseointegration; Procedure; Prosthesis; Reimbursement
1. ABBREVIATIONS
APN: Assessment of Prosthetic Needs
BAP: Bone-anchored prosthesis
CPC: Clinical Prosthetic Clearance
PID: Prosthetic Issue Document
PSP: Prosthetic Service Provider
QALS: Queensland Artificial Limb Service

2. INTRODUCTION
2.1. Background
Current and projected numbers of amputations are alarming. In the US alone, Ziegler-Graham et al (2008) indicated that “One in 190 Americans is currently living with the loss of a limb. Unchecked, this number may double by the year 2050”.[1] Some individuals suffering with lower limb amputation might be non-prosthetic users due to residuum issues (e.g., short residual bone, pain, skin and soft tissue damage).[2] Others will try to use a prosthesis reliant on a socket enveloping their residuum. Unfortunately, the regular manufacturing cost of custom-made sockets is expensive and could range from US$6,203 up to US$20,070 over the first five years following primary amputation.[3-5] Furthermore, these prosthetic users will experience continuous socket-related discomfort. All tend to experience a dramatic decrease in quality of life.[5]

It is becoming apparent that most of these functional issues can be overcome by replacing the socket with a surgically implanted bone-anchored prosthesis (BAP) attached directly to the residual bone using an osseointegrated fixation.[6-14] Few commercial fixations have been trialed and monitored over the last decade.[14, 18-17] Several other fixations are currently in various stages of development in Europe and the US, leading to recent Food and Drug Administration approvals.

BAP engenders major clinical benefits (e.g., prosthetic use, body image, hip range of motion, sitting comfort, ease of donning and doffing, osseoperception, walking ability, sustained extended daily activities) with acceptable clinical risks (e.g., implant stability, rate of infection, effect of a fall, breakage of fixation parts) leading to a significant improvement in health-related quality of life, particularly for young, active and non-vascular individuals with transfemoral amputation.[13, 15-34] Authors often indicated that BAP could potentially reduce some prosthetic, medical and financial burden for health service administrators by reducing the treatment of skin-socket interface problems over the consumer’s lifespan. Indeed, Haggstrom et al (2012) reported that patients with BAP “make significantly fewer visits per year to a prosthetic workshop compared with a similar group using [socket] prostheses. Despite the differences in visits for prosthetic service between the groups the overall prosthetic costs for [BAP] prostheses were comparable with those for [socket] prostheses. We suggest this is due to more sophisticated components that can be used with [BAP]”.[35, 189]

Consequently, governmental organizations are now facing a range of challenges in adjusting their procedures to include fair and equitable financial assistance for consumers choosing BAP.[36] Formal documentation about procedures for the provision of prosthetic services set by funding organizations supporting BAP consumers is sparse.[37-39] Some summary elements of an Australian state’s procedures have been presented but only in abstract form.[44, 45]

Altogether, there is insufficient information to implement a pre-established procedure for prosthetic service provision. The demand from prosthetic care providers and policy-makers for an in-depth presentation of an implementable procedure is yet to be addressed.[46]

2.2. Objectives
The objectives of this study were:
1. To present a procedure implemented by an Australian State organization, with an emphasis on lists of tasks and documents, as well as cost required to support prosthetic care at each stage of treatment with BAP,
2. To share some initial and ongoing obstacles as well as known and suggested facilitators to implementation to be drawn from this experience.

3. METHODS
3.1. Study design
This primary research aiming at developing a governmental procedure for the provision of BAP was designed as an action-research study following guidelines for data-driven collaboration and interactive inquiry process.[47]

The procedure was developed over a research cycle that started in January 2011, approximately six months before the first consumer was treated in Queensland. The timeline and key actions for interconnected planning, doing, studying and acting steps of this development are detailed in Figure 1. The planning step consisted on creating an initial ad hoc procedure combining information from clinical literature and assessment of current Queensland Artificial Limb Service (QALS) procedure during first 6 months. The doing step corresponded to the trialling of the ad hoc procedure during 18 months while monitoring treatment pathways, contribution of each team member and supporting documentation. The studying step
involved analyzing the trialling phase for 6 months using interviews with stakeholders to identify shortcomings and, ultimately, generate the formal procedure. The first 30 months for the three first steps were essential to develop a prosthetic care-focused procedure at each key stage of the treatment for BAP. Finally, the acting step involved implementation of the formal procedure for over 24 months. Stakeholders were informed of new processes and documents, while creating evaluation mechanisms to monitor procedure performances over time (e.g., compliance to procedure, consumer, satisfaction, individual and overall costs) for evidence-based analysis during next action-research cycle of procedure’s revision. The acting step concluded with a collective consensus-based reflection aiming at identifying obstacles and facilitators to implementation to be drawn from this experience.

* Figure 1 *

3.2. Setting

This study was undertaken by the Queensland Artificial Limb Service from the State of Queensland, Australia (Table 1).

In essence, QALS’ role is to ensure an equitable provision and funding of external prosthetic components to eligible residents of Queensland, including those opting for BAP. Eligible consumers must be registered with QALS and (A) be eligible for definitive prosthetic funding support under the Queensland Government’s ‘Artificial Limb Scheme’, or (B) be eligible under the Rehabilitation Appliance Program of the Department of Veteran Affairs.

QALS was particularly prompted to develop a procedure because it is currently facing one of the strongest influx of consumers opting for BAP as Queensland’s tropical heat and humidity make socket-prostheses challenging to wear. Additional drives to develop the procedure including benefits of BAP, economic incentives and managerial decision are provided in Table 1.

* Table 1 *

The development of the procedure was led by a committee set by QALS including: the QALS management team; researchers in health economics; the five first consumers; three Prosthetists referred to as Prosthetic Service Provider (PSP) working in private settings; two clinical teams involved in the surgical implantation of osseointegrated fixations and the rehabilitation with BAP. [48, 49]

3.3. Participants

This study involved all the Queensland-based consumers with transfemoral amputation treated with BAP across Australia between 01/2011 and 06/2015. The only eligibility criterion was to be registered by QALS according to the requirements presented above. Inclusion criterion was that participants must be solely funded by QALS without contribution from other associated organizations. Consequently, consumers jointly funded under the Rehabilitation Appliance Program of the Department of Veteran Affairs were excluded as they might experience different benefits.

3.4. Variables

Several variables were considered during the trial and analysis steps of the development of the procedure (Figure 1) helping QALS to determine a list of relevant tasks and documents enabling prosthetic care at each of the five stages of the BAP treatment (i.e., Pre-op, surgeries, post-op, light limb, definitive limb, ongoing prosthetic care).

Qualitative variables were used to describe the formal procedure allowing the description of what type of actions (e.g., Consult, report, assess, fit) must be undertaken by which specialists (e.g., whole team, PSP, orthopedic surgeons, rehabilitation physicians) at what stage of the treatment.

Quantitative variables were used to characterize fixed costs for PSPs’ contribution including the frequency and duration of intervention of PSPs labor at set hourly fee of $150 to provide prosthetic services and components to consumers.[50] All costs are reported in Australian dollars (1 Australian dollar ≈ 0.71 Euro ≈ 0.60 British pound ≈ 0.76 US dollar) according to 2016-17 prices.

Additional qualitative variables were also considered to establish the list: initial and ongoing obstacles as well as known and suggested facilitators that were either within or outside governmental control using stepwise process leading to consensus including: discussion, initial identification and collaborative modification until final agreement with the lists.

3.5. Data sources

QALS developed the procedure after monitoring literature focusing on dissemination and implementation of procedures using various model’s construct (e.g., Conceptual Model of Implementation Research, Implementation Effectiveness Model, PARIHS) and clinical developments of BAP, particularly the rehabilitation, worldwide and in Australia over a decade.[51-55]

The development of the procedure relied on review of QALS’s formal documentation for current procedure for provision of typical socket prostheses,
specifically the “Schedule of Allowable Hours” and “Schedule of Repairs to Prosthesis”.

4. RESULTS

4.1. Participants

A total of 18 individuals living in Queensland were treated during this study. A total of 16 participants solely funded by QALS were considered while two were discarded as they were covered by Department of Veteran Affairs.

4.2. Descriptive data

The cohort included five (31%) females and 11 (69%) males altogether with an average, standard deviation and age range of 53±10 [38, 67] years, height of 1.73±0.12 [1.51, 1.92] m, mass of 80±20 [51,120] kg, distance between residence and closest point of prosthetic care of 184±164 [8, 506] km and distance between residence and Brisbane capital city of Queensland of 247±331 [9, 1,335] km, respectively. Ten, two and four individuals were amputated due to trauma, tumor or other causes, respectively. The lapse since initial amputation and the beginning of the study was 23±13 [1, 48] years.

4.3. Outcomes data

4.3.1. Description of procedure

A dynamic overview QALS’ formal procedure for provision of BAP as implemented during acting step is presented in Figure 2 detailing the intersections between the treatment stages, tasks, specialists, documents and actions involved in 12 processes during five sequential phases of procedure.

As detailed in Task sections of Figure 2, the series of actions forming the formal procedure include seven processes involving fixed expenses during the course of the BAP treatment. The remaining five processes regulate ongoing expenses for long-term prosthetic care.

Phase 1 (P1) occurs six months pre-operatively. QALS reimburses PSPs for consultation during the screening of consumers (e.g., inclusion and exclusion clinical criteria) and for creation of an individual “passport of service” to record clinical and prosthetic milestones (e.g., patient journey). QALS does not provide funding for surgical costs.

Phase 2 (P2) occurs between surgeries and post-operative stages and lasts approximately two months. QALS reimburses PSPs for a consultation before consumers start the rehabilitation program, establishing base line prosthetic assessment and completing the passport. QALS does not provide funding associated with inpatient rehabilitation care.

Phase 3 (P3) occurs approximately six months after the surgery. It involves fitting light prosthesis during the first part of rehabilitation program. Orthopedic Specialists complete and email to QALS the first Clinical Prosthetic Clearance (CPC) form, indicating that consumers are ready to progress onto rehabilitation with a light prosthesis. This temporary prosthesis required to complete the osseointegration is built with basic components. PSPs are encouraged to use consumer’s pre-existing prosthetic components when possible. PSPs list the components required with justification on an Assessment for Prosthetic Needs (APN) form and submit to QALS for funding approval. PSPs are responsible for evaluating, designing, manufacturing and fitting the light prosthesis. QALS reimburses PSPs based on the approved APN form, completion of the Prosthetic Issue Document (PID) form and updating of the passport.

Phase 4 (P4) occurs during the last six months upon completion of the rehabilitation program with the light prosthesis. It involves assessing and fitting the definitive prosthesis. PSPs consult with Rehabilitation Specialists to complete a second CPC form. Physiotherapists conduct a mobility assessment using standard instrument (i.e., Amputee Mobility Predictor Assessment Tool). The prosthetic assessment is also based on PSP’s expert judgment considering a range of consumers’ circumstances including, but not limited to, lifestyle needs, work commitments, social interactions and home environments. PSPs are also encouraged to consider consumers’ pre-existing components. QALS recommends that a basic definitive limb must include a connector, protective device, an economical microprocessor-controlled knee and a foot with torque absorber, to ensure safe ambulation (e.g., fall, protective loading profile) during activities of daily living. Only Therapeutic Goods Administration certified and QALS registered components are considered acceptable. PSPs include the final list of components and justification on an APN form to be approved for funding by QALS and instruct consumers on basic component care and must advise them of their prosthesis’ loading and activity limitations (e.g., water conditions, physical activities, environment, fall safety). Finally, QALS reimburses PSPs to assess, design, manufacture, fit and adjust the definitive prosthesis. A PID is completed when the definitive prosthesis is trialled and the passport is updated with treatment and services provided. Furthermore, consumers are asked to complete the acquittal and quality assurance survey upon acceptance of their definitive prosthesis.

Phase 5 (P5) involves long-term ongoing prosthetic care after initial fitting of the definitive prosthesis. PSPs are responsible for evaluating, fitting and reporting all activities related to services.
and repairs of definitive prostheses. Consumers’ prosthetic needs can be re-assessed if needed using the process presented above. Fitting of new components must follow the conditions of use and government guideline (e.g., components manufacturing warranties, periods of use). PSPs are responsible for completing the passport when changes are conducted.

The performance of the procedure is evaluated using the standard QALS’ Prosthetic Service Evaluation Form (e.g., QALS Form P009) and monitoring of verbal and written feedback sent to QALS Consumer Advisory Committee as well as reporting individual and overall costs for BAP.

4.3.2. Cost of PSP involvements

The breakdown of frequency and duration of intervention of PSPs labour included at the heart of formal QALS’ procedure is provided in Table 2. The studying step of action research (Figure 1) led to an agreement between stakeholders that a total of 22 hours of labor corresponding to $3,300 were sufficient to accommodate both PSPs’ prosthetic care standards and QALS’ financial resources. PSP labor allocated to P1, P2, P3 and P4 included 2.5, 2.5, 6.5 and 10.5 hours corresponding to 11 ($375), 11 ($375), 30 ($975) and 48 ($1,575) percent of the total labor cost, respectively. PSPs could spend up to 4, 2, 14 and 2 hours for consultation, evaluation, fitting and reporting activities corresponding to 18 ($600), 9 ($300), 64 ($2,100) and 9 ($300) percent of the total labor cost, respectively. As expected, PSPs spend the vast majority of the time (64%) focusing on prosthetic care only (e.g., fitting, alignment). Nonetheless, they also spend some significant effort (36%) to conduct other, perhaps more clinical and managerial, underlying activities. PSPs were logically involved in provision of definitive limbs and subsequent ongoing long-term prosthetic care (P5) upon completion of rehabilitation applying typical QALS’ procedures.

5. DISCUSSION

5.1. Key results

This study showed that:

- The procedure developed between 01/2011 and 06/2015 included seven processes involving fixed expenses during the treatment and five processes regulating ongoing prosthetic care expenses.
- Prosthetic care required 22 hours of labor corresponding to $3,300 per patient during rehabilitation. Prosthetists spend 64% and 36% of their time focusing on prosthetic care and other underlying activities, respectively.
- Stepwise process identified a list of initial and ongoing obstacles as well as known and suggested facilitators that were deemed within and outside the governmental control.

5.2. Interpretations

5.2.1. Adjustments

The proposed procedure was largely inherited from previous procedures for conventional prostheses that are more likely to be used by most governmental organizations. However, significant adjustments were made to accommodate specific BAP prosthetic care.

The first adjustment related to the involvement of qualified prosthetists. At this stage, PSPs’ scope of practice and activities were compliant with Australian competency standards for qualified prosthetists. However, it is anticipated that prosthetists might become the “gate keeper” for patients with BAP, which could possibly put them in a more predominant case manager role. They will remain primarily in charge of regular and incidental prosthetic care (e.g., maintenance, adjustments, loading profile management, breakage of fixation part after fall). In addition, they will be more likely to become the first point of care to prevent, diagnose and refer for treatment at initial signs of infections, for example.
Another adjustment was the funding of light limb during rehabilitation. Typically, governmental organizations provide essentially definitive prostheses. However, the success of treatment relies on progressive loading for strong bonding between bone and fixation called osseointegration. This requires the use of a light limb during rehabilitation program corresponding to the Stage 3 of the procedure. Built with basic components this temporary prosthesis only provides limited range of movement and restricted ambulation. Attempt to minimize costs were made by encouraging PSPs to use of patient’s own pre-existing components when possible without compromising safety (e.g., single axis knees, pylon, feet).

The last significant adjustment involved the allocation of advanced microprocessor-controlled knees providing critical biomechanical advantages but costing up to $60,000 per unit. This might be beyond the typical standard funding guidelines for most governmental organizations, even for the most functional consumers with very active lifestyles. Review of standards for allocation of prosthetic knee units was needed since consumers with BAP must be fitted with microprocessor-controlled knees mainly for safety reasons (e.g., loading profile, fall prevention).\textsuperscript{[20, 21, 31, 32, 58-60]} Fortunately, this adjustment was eased by agreements with prosthetic suppliers to provide QALS consumers with an affordable component package for under $20,000, including appropriate knee and foot units.

5.2.2. Manageable obstacles

The step revealed that the current number of processes remains on obstacle within the governmental control to overcome. As presented in Figure 2, the existing procedure relies essentially on PSPs to coordinate and document up to 12 processes per consumer during the first year. The underlying paper work is time-consuming and burdensome. Therefore, efforts could be made to streamline systematic processes around provision of expensive items (e.g., light and definitive limbs) while ensuring responsibility of clinical stakeholders, quality and control over expenses.

As identified during the planning step, an initial obstacle outside governmental control was the lack of a definitive rehabilitation program, particularly for the treatment with press-fit fixation for transfemoral amputations. This issue is resolving as particular rehabilitation programs for this case-mix are becoming more established.\textsuperscript{[8-11, 13, 16, 63-67]} Nonetheless, this has led to uncertainty in the relevance and timing of PSP involvement for pre-operative, surgery and post-operative prosthetic care.

Unfortunately, a lack of specific rehabilitation programs is likely to remain ongoing and demand consistent attention in upcoming years with anticipated emergence of new fixations. These treatments might involve rehabilitation programs different from those currently available and, consequently, require different PSPs involvements.

Sustaining and evaluating this complex procedure are some of the main ongoing challenges partially under the control of governmental organization due to continual BAP clinical improvements (e.g., surgical procedures, long terms outcomes) and development of prosthetic components (e.g., biomechanical performance, cost).

5.2.3. Transferable facilitators

The experience reported here revealed several key facilitators for implementation that are transferable to other settings including, but not limited to:

- Early and consistent consultations of stakeholders to warrant appropriateness of the intervention and process compliance of consumers, prosthetists and clinicians (e.g., orthopedic surgeons, physiotherapists),
- Adapting existing processes rather than creating new ones while taking into consideration involvement of PSPs, fitting of light limb during rehabilitation and need for microprocessor-controlled knees units,
- Use a document to track patient’s journey (e.g., passport of service) to contribute to patient empowerment and to facilitate continuum of care particularly for multidisciplinary services performed interstate.
- Establishing systematic processes focusing on assessment, approval before reimbursement, provision and reporting of expensive items.\textsuperscript{[68]}

5.3. Limitations

The procedure has been implemented over two years for 18 consumers. All participants had unilateral transfemoral amputation. They were mainly located in metropolitan areas in reasonable proximity of PSPs. Only a small number of dedicated PSPs and clinicians were involved.

5.4. Generalization

The overall two-year duration of observation allowed us considering a convenient cohort size of 16 participants. This number might be considered
sufficient given the limited number of patients accessing this type of treatment (e.g., eligibility, out-of-pocket costs). This sample size is slightly above the average of 14 participants in studies in the field of prosthetics. Furthermore, the population could be possibly representative as it corresponded to 13% and 3.2% of existing population estimated at 120 in Australia and 500 worldwide, respectively.

On the other hand, only a narrow case-mix limited to individuals with transfemoral amputation was considered. Also, only one action research cycle was conducted.

Finally, one additional limitation to generalisation is that this procedure was only a reflection of an Australian State organisation focusing on prosthetic care. Treatment pathways for provision of BAP could differ between jurisdictions. For example, costs for BAP fall mainly under the rim of rehabilitation providers and not PSPs only in some European countries. In the US, active duty members treated through a Department of Defence research protocol supported by Food and Drug Administration approved Humanitarian Device Exemptions may apply for a waiver under the Supplemental Health Care Program process.

Altogether, one can argue that generalization of these study outcomes must be considered carefully. Furthermore, the potential for scalability of this procedure within and between jurisdictions also remains to be confirmed more particularly its capacity to integrate more complex case mixes (e.g., transtibial, multi-level amputations), the geographical spread of consumers extending to rural areas with limited access to a PSP, the increasing number of treatment sites in Australia and abroad as the surgery becomes more routinely performed.

5.5. Future studies

Clearly, there will be a need to further extend this procedure to accommodate future developments in BAP including, but not limited to, growing number of consumers, broadening of case mix, changes to surgical procedures, emergence of multiple treatment centers, constant developments of prosthetic components. Effects of these changes in the development, implementation and evaluation of QALS’ procedure could be achieved through a range of subsequent studies.

Further longitudinal studies will focus on systematic evaluation of stakeholders’ compliance and satisfaction with the procedure including primarily consumers and PSPs over an extended period of time (e.g., six-year funding cycle). Satisfaction of PSPs will be of particular interest as the BAP could possibly lead to loss of income due to reduction of socket manufacturing. Consequently, a cross-comparison of compensation provided by QALS ($3,300) will be needed to establish whether BAP represents a loss, comparable or increased revenues for PSPs.

Additional cross-sectional studies will focus on procedure performances in combination with measure of impact of BAP on physical functioning (e.g., level of activities of daily living), health related quality of life (e.g., physical and mental components), employment (e.g., return to work, reduction of sick leave) and cost-effectiveness of BAP compared to socket prostheses (e.g., re-use of pre-existing components, cost-comparison, cost per quality adjusted life year, incremental cost-effectiveness ratio) and other orthopedic device (e.g., knee and hip implants).

Altogether, new information will facilitate product development and effective adoption of procedure for a sustainable provision of BAP.

6. CONCLUSIONS

For the first time an overview of how a procedure from one governmental organization could provide bone-anchored prostheses is presented. The experience reported here is a stepping-stone providing a working plan for both development and implementation of procedure to stakeholders responsible for policies around care of individuals fitted with bone-anchored prostheses.

7. ACKNOWLEDGMENT

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8. COMPLIANCE WITH ETHICAL STANDARDS

- 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.
- The University of the Sunshine Coast received funding from QALS to conduct the study.
- Laurent Frossard, Adjunct Professor at the University of the Sunshine Coast and Director of YourResearchProject Pty Ltd was appointed as consultant by the University of the Sunshine

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Coast to manage this project of research including collection, analysis and reporting procedure and cost data.

- Laurent Frossard, Director of YourResearchProject Pty Ltd has work as consultant for several organisations on non-related educational programs and projects of research to work recording of loading data, development of database to record clinical outcomes as well as drafting of grants and manuscripts.
- Gregory Merlo declares that he has no conflict of interest.
- Tanya Quincey is a client service officer at QALS and receives a salary from Metro-South Hospital and Health Service, Queensland Health.
- Brendan Burkett is the first Australian with transfemoral amputation fitted with Integral Leg Prosthesis (Orthodynamics, UK) fixation.
- Debra Berg is the Manager of QALS and receives a salary from Metro-South Hospital and Health Service, Queensland Health.

9. DATA AVAILABILITY STATEMENT
- All data generated or analysed during this study are included in this published article.
- The QALS procedure for provision bone-anchored prostheses to Queensland consumer generated during the current study is available from the corresponding author on reasonable request.
- Generic information about QALS procedures is available at: https://www.health.qld.gov.au/qals

10. AUTHOR CONTRIBUTIONS
- Laurent Frossard has contributed to the management of the whole study including design of methods, collect of information, analysis and interpretation of data and writing of manuscript.
- Gregory Merlo has contributed to development of the methods, analysis and interpretation of data and writing of the manuscript.
- Tanya Quincey had contributed to collect of information and review of manuscript.
- Brendan Burkett has contributed to management of the project, interpretation of data and review of manuscript.
- Debra Berg has contributed to management of the project, collect of information, interpretation of data and writing of manuscript.

11. TO KNOW MORE

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Table 1. Contextual information about the study setting (QALS: Queensland Artificial Limb Service, BAP: Bone-anchored prosthesis, TFA: Individuals with transfemoral amputation, PSP: Prosthetic Service Provider).

| Descriptor                                    | Information                                                                 |
|-----------------------------------------------|-----------------------------------------------------------------------------|
| **Geographical information about State of Queensland** |                                                                                     |
| Capital city                                  | Brisbane                                                                    |
| Population                                    | 4.7 million                                                                 |
| Size                                          | 1.8 million km²                                                               |
| Average temperature                           | Summer: 35°C - 21°C, Winter: 22°C - 10°C                                      |
| Average humidity                              | Summer: 50%, Winter: 65% - 75%                                               |
| **Description of QALS**                       |                                                                                     |
| Location                                      | Brisbane                                                                    |
| State organisation                            | Relates to the Medical Aids Subsidy Scheme, Metro South Health and ultimately the Queensland Government Minister of Health |
| Role                                          | Provide prosthetic services (e.g., artificial limbs) to eligible residents of Queensland, under the State Government’s ‘Artificial Limb Scheme’ |
| Yearly budget                                  | $5.4M                                                                        |
| Number of consumers registered                | Over 7,000                                                                   |
| Number of active consumers per year           | Over 3,000                                                                   |
| Number of active consumers with TFA           | Over 600 (20%)                                                               |
| Number of PSPs                                | 6 to 10                                                                      |
| **Drives to develop procedure**               |                                                                                     |
| Demand from consumers                         | QALS could face requests from up to 550 consumers to be fitted with BAP       |
| Benefits of BAP                                | Countless anecdotal accounts of BAP clinical benefits in grey and professional reports |
| Economic incentives                            | Preliminary scientific evidence demonstrating clinical benefits of BAP       |
| Managerial decision                           | Possible cost-effectiveness of BAP compared to socket prosthesis             |
|                                              | Upcoming consumers could cost tax payers over $60M in the next 12 years     |
|                                              | Aspiration to be a key player in development of procedure worldwide         |
Table 2. Cost breakdown of Prosthetic Service Provider (PSP) labour ($150 per hour) included in the schedule of allowable fixed expenses in QALS’ procedure to provide prosthetic services and components to consumers fitted with bone-anchored prostheses.

| Treatment stage | Procedure phase | ID  | Items                        | Timeline | Cost PSP Labour ($)|
|-----------------|----------------|-----|------------------------------|----------|--------------------|
| Pre-op          | P1             | P1-A| Screening consultation       | -3.0     | $ 300              |
| Pre-op          | P1             | P1-B| Creation of passport         | -2.0     | $ 75               |
| Surgery         | P2             | P2-A| Consultation after surgeries | 0.5      | $ 300              |
| Surgery         | P2             | P2-B| Completion of passport       | 1.0      | $ 75               |
| Rehab           | P3             | P3-A| Pre-fitting of light limb    | 1.5      | $ 150              |
| Rehab           | P3             | P3-B| Fitting of light limb        | 2.0      | $ 600              |
| Rehab           | P3             | P3-C| Completion of passport       | 2.5      | $ 75               |
| Rehab           | P4             | P4-A| Pre-fitting of definitive limb| 3.0      | $ 150              |
| Rehab           | P4             | P4-B| Fitting of definitive limb   | 3.5      | $ 1,500            |
| Rehab           | P4             | P4-C| Completion of passport       | 4.0      | $ 75               |
| **Total fixed** |                |     |                              | **22.0** | **$ 3,300**        |
Table 3. Overview initial and ongoing obstacles identified after implementation of formal procedure for provision of bone-anchored prostheses (PSP: Prosthetic Service Provider).

| Obstacles                                                                 | Governmental control |
|--------------------------------------------------------------------------|----------------------|
| **Initial Obstacles**                                                    |                      |
| • Estimation of PSPs hours for pre-op, surgery and post-op prosthetic care | x                    |
| • Review of QALS paradigm for allocation of advanced knee unit            | x                    |
| • Absence of procedures for pre-op, surgery and post-op care              | x                    |
| • Difficulties to extract easily individuals and overall costs for BAP consumers | x |
| • Dealing with treatment occurring interstate and possibly overseas       | x                    |
| • Lack of definitive rehabilitation guideline for press-fit fixation       |                      |
| • Lack of guidelines for BAP prosthetic care (e.g., choice of knee unit)  | x                    |
| • Limited scientific evidence about clinical harms for press-fit fixation | x                    |
| • Limited funding to perform action research                             | x                    |
| **Ongoing Obstacles**                                                    |                      |
| • Reduction of the number of processes before Phase 5 of the procedure    | x                    |
| • Funding for ongoing monitoring of procedure (e.g., cost, satisfaction)  | x                    |
| • Slight broadening of PSPs role (e.g., case management)                  | x                    |
| • Standardisation of passport of service (e.g., creation of electronic version) | x |
| • Continual evolutions of surgical procedures (e.g., single stage)        | x                    |
| • Constant developments of conventional prosthetic components             | x                    |
| • Unpredictable developments of specific components for BAP (e.g., connector) | x |
| • Change of national framing policy (e.g., National Disability Insurance Scheme) | x |
Table 4. Overview of known and suggested facilitators to implementation identified after implementation of formal procedure for provision of bone-anchored prostheses (PSP: Prosthetic Service Provider, AMPAT: Amputee Mobility Predictor Assessment Tool; FDA: Food and Drug Administration, SF36: Short From 36, Q-TFA: Questionnaire for Transfemoral amputees).

| Known Facilitators                                                                 | Governmental control |
|-----------------------------------------------------------------------------------|----------------------|
| • Engage early with stakeholders, particularly PSPs                                | x                    |
| • Adapt existing processes rather than creating ones                               | x                    |
| • Create of passport of service (e.g., interstate care)                            | x                    |
| • Assess actual prosthetic needs from PSPs and consumer’s perspectives             | x                    |
| • Clarify PSPs role and responsibilities (e.g., case manager)                      | x                    |
| • Use of standard instruments to assess needs and outcomes (e.g., AMPAT)           | x                    |
| • Create database to monitor individual and overall costs                          | x                    |
| • Clarify PSPs role and responsibilities (e.g., case manager)                      | x                    |
| • Negotiate regularly with suppliers of components                                | x                    |
| • Will from QALS’ management team to facilitate changes                            | x                    |
| • Understand rehabilitation and safety requirements                                | x                    |

| Suggested Facilitators                                                           | Governmental control |
|-----------------------------------------------------------------------------------|----------------------|
| • Approve reimbursement before most expensive items                               | x                    |
| • Analysis of quarterly reports for progress, compliance, cost and satisfaction   | x                    |
| • Use of standard instruments to assess outcomes (e.g., SF36, Q-TFA)              | x                    |
| • Educate PSPs about ways to limit cost (e.g., re-use of components)             | x                    |
| • Monitor national and international developments (e.g., FDA approval)           | x                    |
| • Set processes to assess benefits of treatment (e.g., daily steps count)         | x                    |
| • Engage continuously with local clinical teams (e.g., specifics of rehabilitation)| x                    |
| • Engage continuously with suppliers and manufacturers of components             | x                    |
| • Increase funding for action research to develop procedure                       | x                    |
Figure 1. Action-Research process outlining of the timeline and actions for each of the typical steps used to develop the formal procedure for provision of bone-anchored prosthesis (BAP). (PSP: Prosthetic Service Provider, CPC: Clinical Prosthetic Clearance, APN: Assessment of Prosthetic Need, PID: Prosthetic Issue Document)

| Step 1 – Plan: Create ad-hoc procedure |
|---------------------------------------|
| **Project start** (01/2011)           |
| **First consumer** (06/2011)          |
| • Review BAP literature about:        |
|   o Rehabilitation programs          |
|   o Prosthetic fitting requirements   |
|   o Cost-effectiveness               |
| • Assess suitability of existing procedures including: |
|   o Review Schedule of Allowable Hours (51 items) |
|   o Review Schedule of Repairs to Prosthesis (47 items) |
| • Create ad-hoc procedure |
|   o Identify key stakeholders        |
|   o Draft role and responsibilities of team members |
|   o Draft processes to provide prosthetic care |
|   o Modify existing supporting forms  |

| Step 2 – Do: Trial ad-hoc procedure |
|-------------------------------------|
| **First consumer** (06/2011)        |
| **Tenth consumer** (01/2013)        |
| • Monitor treatment pathways including: |
|   o Inclusion and exclusion criterion |
|   o Lapse between rehabilitation milestones |
|   o Timing of fitting with light and definitive limbs |
| • Monitor contribution of each team member including: |
|   o Activities of Orthopaedic and Rehabilitation Specialists, Physiotherapists |
|   o Hours and cost for PSPs contribution |
| • Monitor supporting documentation including: |
|   o Suitability of supporting forms |
|   o Creation of “passport of service” |

| Step 3 – Study: Analysis ad-hoc procedure |
|------------------------------------------|
| **Tenth consumer** (01/2013)             |
| **Consultation** (06/2013)               |
| • Interviews with stakeholders focusing on: |
|   o Quality of prosthetic care           |
|   o Benefits and limitations of ad-hoc procedure |
| • Address perceived limitations including: |
|   o Number of PSP hours to manage prosthetic care |
|   o Choice of components for light limb   |
|   o Suitability of components for definitive limb |
| • Creation of formal procedure (Documents and tasks) |
|   o Formalise role and responsibilities of PSPs |
|   o Formalise processes to provide prosthetic care |

| Step 4 – Act: Implement formal procedure |
|-----------------------------------------|
| **Consultation** (06/2013)              |
| **Implementation** (06/2015)             |
| • Implementation |
|   o Inform stakeholders of formal procedure |
|   o Monitor performance of procedure     |
| • Reflection |
|   o Identify initial and ongoing obstacles |
|   o Identify known and suggested facilitators |

Figure 2. Overview of intersections between the stages of the bone-anchored prosthesis (BAP) treatment and the task, specialist, document and action in each process during five phases (P1, P2, P3, P4 and P5) of the procedure. PSP: Prosthetic Service Provider, Ortho: Orthopaedic specialist, CPC: Clinical Prosthetic Clearance,
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APN: Assessment of Prosthetic Need, Rehab: Rehabilitation specialist, AMPAT: Amputee Mobility Predictor Assessment Tool, PID: Prosthetic Issue Document

**Treatment for BAP**

| Stage | Purpose | Activity | Specialist | Document | Task | Phase |
|-------|---------|----------|------------|----------|------|-------|
| Pre-op | Screening | Consult | Team | Reimburse | P1 |
|       | Selection | Report | PSP |           | Reimburse |
| Surgeon | Implantation | Consult | Ortho | Reimburse | P2 |
|         |           | Report | PSP | Passport | Reimburse |
| Post-op | Rehab | Assess | Ortho | Email | Review | P3 |
| Light | Fitting Component Adjustment | Fit | PSP | CPC form | Approve | |
|        | Report | Email | APN | PID | Approve | |
| Definitive | Fitting Component Adjustment | Report | PSP | PID | Approve | P4 |
|         | Assess | AMPAT | APN | PID | Approve | |
|         | Fit | CPC form | APN | Passport | Reimburse |
|         | Report | Acquittal | | | |
| Defining prosthetic care | Maintenance | Assess | PSP | APN | Approve | P5 |
|         | Fit | PID | | | |
|         | Report | Voucher | | | |
|         | | Passport | | | |
|         | | Reimburse | | | |

Fixed expenses | Ongoing expenses