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ORIGINAL RESEARCH ARTICLE

Development of a Procedure for the Government Provision of Bone-Anchored Prosthesis Using Osseointegration in Australia

Laurent Frossard[1,2] · Gregory Merlo[1,3] · Tanya Quincey[4] · Brendan Burkett[2] · Debra Berg[4]

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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 (BAPs) over socket-suspended prostheses.

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

Methods This research aimed at developing a governmental procedure for the provision of BAPs 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 January 2011 and June 2015, included seven processes involving fixed expenses during treatment and five processes regulating ongoing prosthetic care expenses. Prosthetic care required 22 h of labor, corresponding to AUD$3300 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 the 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 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, and 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 the care of individuals choosing osseointegration for BAPs.

✉ Laurent Frossard
laurentfrossard@outlook.com

Gregory Merlo
gb.merlo@qut.edu.au

Tanya Quincey
Tanya.Quincey@health.qld.gov.au

Brendan Burkett
BBurkett@usc.edu.au

Debra Berg
debra.berg@health.qld.gov.au

[1] Queensland University of Technology, Brisbane, QLD, Australia

[2] University of the Sunshine Coast, Maroochydore, QLD, Australia

[3] Australian Centre for Health Services and Innovation, Brisbane, QLD, Australia

[4] Queensland Artificial Limb Service, Brisbane, QLD, Australia

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 (BAPs) is yet to be addressed.

A procedure for the provision of BAPs could include seven processes involving fixed expenses during treatment and five processes regulating ongoing prosthetic care expenses.

A total of 22 h of prosthetist's labor, corresponding to AUD$3300, was deemed sufficient to provide a BAP to an individual with a transfemoral amputation during the rehabilitation program.

1 Introduction

1.1 Background

Current and projected numbers of amputations are alarming. In the US alone, Ziegler-Graham et al. 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 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], while 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$6203 up to US$20,070 over the first 5 years following primary amputation [3, 4]. 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 [4, 15–17], while several other fixations are currently in various stages of development in Europe and the US, leading to recent US FDA approval.

A 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 nonvascular individuals with transfemoral amputation [13, 15–34]. Authors often indicated that BAPS 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. reported that patients with BAPs "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] were comparable with those for [socket] prostheses. We suggest this is due to more sophisticated components that can be used with [BAP]" [35].

Consequently, governmental organizations are now facing a range of challenges in adjusting their procedures to include fair and equitable financial assistance for consumers choosing a BAP [36]. Formal documentation about procedures for the provision of prosthetic services set by funding organizations supporting BAP consumers is sparse [37–43]. 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].

1.2 Objectives

The objectives of this study were to (1) 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 BAPs, and (2) share some initial and ongoing obstacles as well as known and suggested facilitators to implementation to be drawn from this experience.

2 Methods

2.1 Study Design

This primary research aimed at developing a governmental procedure for the provision of BAPs was designed as an action research study following guidelines for data-driven collaboration and interactive inquiry processes [47].

The procedure was developed over one action research cycle that started in January 2011, approximately 6 months before the first consumer was treated in Queensland. The timeline and key actions for the interconnected planning,

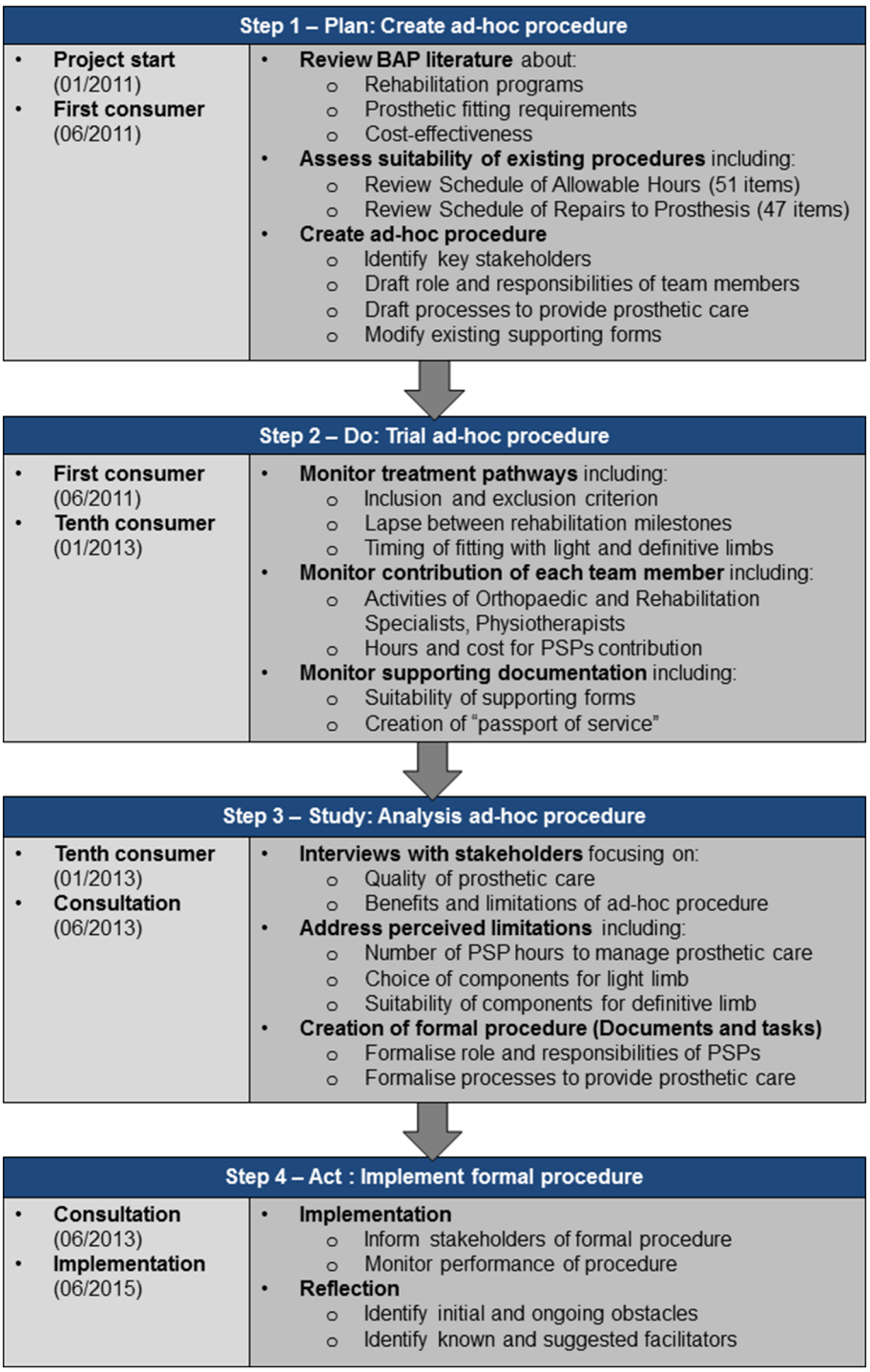

Fig. 1 Action research process outlining the timeline and actions for each of the typical steps used to develop the formal procedure for provision of bone-anchored prosthesis. *BAP* bone-anchored prosthesis, *PSPs* Prosthetic Service Providers

doing, studying and acting steps of this development are detailed in Fig. 1. The 'planning' step consisted of creating an initial ad hoc procedure combining information from the clinical literature and assessment of current Queensland Artificial Limb Service (QALS) procedures during the first 6 months, while the 'doing' step corresponded to the trialing of the ad hoc procedure over an 18-month period while monitoring treatment pathways, contribution of each team member, and supporting documentation. The 'studying' step involved analyzing the trialing phase for 6 months using interviews with stakeholders to identify shortcomings and, ultimately, generate the formal procedure. The first 30 months for the first three steps were essential to develop a prosthetic care-focused procedure at each key stage of the treatment for BAPs. Finally, the 'acting' step involved implementation of the formal procedure over 24 months.

Stakeholders were informed of new processes and documents, while creating evaluation mechanisms to monitor procedure performances over time (e.g. compliance with procedure, consumer, satisfaction, individual and overall costs) for evidence-based analysis during the next action research cycle of the procedure's revision. The acting step concluded with a collective consensus-based reflection aimed at identifying obstacles and facilitators to implementation to be drawn from this experience.

2.2 Setting

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

In essence, the role of the QALS is to ensure an equitable provision and funding of external prosthetic components to eligible residents of Queensland, including those opting for a BAP. Eligible consumers must be registered with the QALS and (1) be eligible for definitive prosthetic funding support under the Queensland Government's 'Artificial Limb Scheme', or (2) be eligible under the Rehabilitation Appliance Program of the Department of Veteran Affairs.

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

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

Table 1 Contextual information about the study setting

Descriptor	Information
Geographical information about the State of Queensland	
Capital city	Brisbane
Population	4.7 million
Size	1.8 million km^2
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 organization	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	$5.4 M
Number of consumers registered	Over 7000
Number of active consumers per year	Over 3000
Number of active consumers with TFA	Over 600 (20%)
Number of PSPs	6–10
Drives to develop procedure	
Demand from consumers	QALS could face requests from up to 550 consumers to be fitted with a BAP
Benefits of BAP	Countless anecdotal accounts of BAP clinical benefits in grey and professional reports
	Preliminary scientific evidence demonstrating clinical benefits of BAP
Economic incentives	Possible cost effectiveness of BAP compared with socket prosthesis
	Upcoming consumers could cost taxpayers over $60 M in the next 12 years
Managerial decision	Aspiration to be a key player in development of the procedure worldwide

QALS Queensland Artificial Limb Service, *BAP* bone-anchored prosthesis, *TFA* transfemoral amputation, *PSPs* Prosthetic Service Providers

2.3 Participants

This study involved all Queensland-based consumers with transfemoral amputation treated with BAP across Australia between January 2011 and June 2015. The only eligibility criterion was to be registered by the QALS according to the requirements presented above. Inclusion criterion was that participants must be solely funded by the 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.

2.4 Variables

Several variables were considered during the trial and analysis steps of the development of the procedure (Fig. 1), helping the QALS to determine a list of relevant tasks and documents enabling prosthetic care at each of the five stages of BAP treatment (i.e. preoperative, surgeries, postoperative, 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, PSPs, orthopedic surgeons, rehabilitation physicians) and at what stage of the treatment. Quantitative variables were used to characterize fixed costs for the PSPs' contribution, including the frequency and duration of intervention of the PSPs' labor, at a set hourly fee of $150, to provide prosthetic services and components to consumers [50]. All costs are reported in Australian dollars (1 Australian dollar $\approx$ €0.71 $\approx$ £0.60 $\approx$ US$0.76) according to 2016–2017 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 a stepwise process, leading to consensus, including discussion, initial identification and collaborative modification, until final agreement with the lists was reached.

2.5 Data Sources

The QALS developed the procedure after monitoring the literature focusing on dissemination and implementation of procedures using the construct of various models (e.g. Conceptual Model of Implementation Research, Implementation Effectiveness Model, Promoting Action on Research Implementation in Health Services [PARIHS]) and clinical developments of BAPs, particularly rehabilitation, worldwide and in Australia, over a decade [51–55].

Development of the procedure relied on review of the QALS's formal documentation for current procedures for the provision of typical socket prostheses, specifically the 'Schedule of Allowable Hours' and 'Schedule of Repairs to Prosthesis'.

3 Results

3.1 Participants

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

3.2 Descriptive Data

The cohort included five (31%) females and 11 (69%) males, with an average age $\pm$ standard deviation (range) of 53 $\pm$ 10 years (38–67), height of 1.73 $\pm$ 0.12 meters (1.51–1.92), mass of 80 $\pm$ 20 kg (51–120), distance between residence and closest point of prosthetic care of 184 $\pm$ 164 km (8–506), and distance between residence and Brisbane (the capital city of Queensland) of 247 $\pm$ 331 km (9–1335). Ten, two, and four individuals were amputated due to trauma, tumor, or other causes, respectively, and the lapse since initial amputation and the beginning of the study was 23 $\pm$ 13 years (1–48).

3.3 Outcomes Data

3.3.1 Description of the Procedure

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

As detailed in the 'task' sections of Fig. 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 6 months preoperatively. The QALS reimburses PSPs for consultations 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). The QALS does not provide funding for surgical costs.

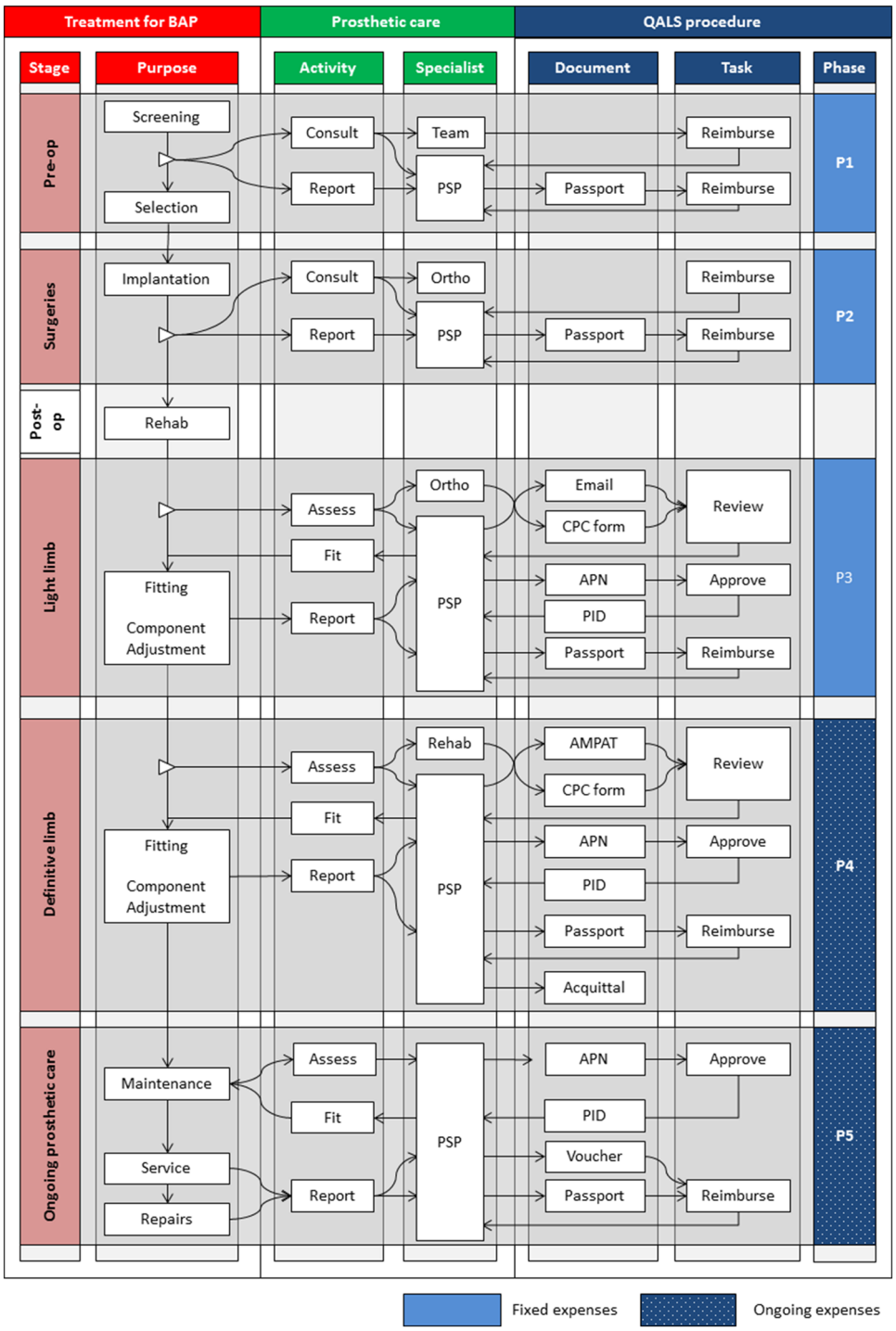

Fig. 2 Overview of intersections between the stages of the bone-anchored prosthesis treatment and the task, specialist, document and action in each process during five phases (P1, P2, P3, P4 and P5) of the procedure. *BAP* bone-anchored prosthesis, *QALS* Queensland Artificial Limb Service, *PSP* Prosthetic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

Phase 2 (P2) occurs between the surgery and postoperative stages and lasts approximately 2 months. The QALS reimburses PSPs for a consultation prior to consumers starting the rehabilitation program, establishing baseline prosthetic assessment, and completing the passport. The QALS does not provide funding associated with inpatient rehabilitation care.

Phase 3 (P3) occurs approximately 6 months after surgery and involves fitting a light prosthesis during the first part of the rehabilitation program [56, 57]. Orthopedic specialists complete and e-mail to the 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 process is built with basic components. PSPs are encouraged to use a 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 them to the QALS for funding approval. PSPs are responsible for evaluating, designing, manufacturing, and fitting the light prosthesis, while the 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 6 months upon completion of the rehabilitation program with the light prosthesis, and involves assessing and fitting the definitive prosthesis. PSPs consult with rehabilitation specialists to complete a second CPC form, and physiotherapists conduct a mobility assessment using a standard instrument (i.e. Amputee Mobility Predictor Assessment Tool). The prosthetic assessment is also based on the expert judgment of PSPs, considering a range of consumer 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. The 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 [20, 21, 31, 32, 58–61]. Only Therapeutic Goods Administration-certified and QALS-registered components are considered acceptable. PSPs include the final list of components, along with justification, on an APN form to be approved for funding by the QALS. They instruct consumers on basic component care and must advise them of the loading and activity limitations of their prosthesis (e.g. water conditions, physical activities, environment, fall safety). Finally, the QALS reimburses PSPs to assess, design, manufacture, fit, and adjust the definitive prosthesis. A PID is completed when the definitive prosthesis is trialed and the passport is updated with the 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 the servicing and repair of definitive prostheses. Consumers' prosthetic needs can be reassessed if needed, using the process presented above. The fitting of new components must follow the conditions of use, as well as government guidelines (e.g. component 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 verbal and written feedback sent to the QALS Consumer Advisory Committee, as well as reporting individual and overall costs for a BAP.

3.3.2 Cost of Prosthetic Service Provider Involvement

A breakdown of the frequency and duration of intervention of the PSPs' labour included at the heart of the formal QALS procedure is provided in Table 2. The 'studying' step of the action research cycle (Fig. 1) led to an agreement between stakeholders that a total of 22 h of labor, corresponding to $3300, were sufficient to accommodate both PSPs' prosthetic care standards and the QALS' financial resources. PSP labor allocated to P1, P2, P3, and P4 included 2.5, 2.5, 6.5, and 10.5 h, corresponding to 11% ($375), 11% ($375), 30% ($975), and 48% ($1575) of the total labor cost, respectively. PSPs could spend up to 4, 2, 14 and 2 h for consultation, evaluation, fitting, and reporting activities, corresponding to 18% ($600), 9% ($300), 64% ($2100), and 9% ($300) of the total labor cost, respectively. As expected, PSPs spend the vast majority of time (64%) focusing on prosthetic care only (e.g. fitting and alignment). Nonetheless, they also spend some significant effort (36%) conducting other, perhaps more clinical and managerial, underlying activities. PSPs were logically involved in the provision of definitive limbs and subsequent ongoing long-term prosthetic care (P5) upon completion of rehabilitation, applying typical QALS procedures.

3.3.3 Obstacles and Facilitators

The list of obstacles and facilitators identified during the last part of the 'acting' step are provided in Tables 3 and 4, respectively. A total of 17 obstacles were collectively identified, including nine initial and eight ongoing obstacles. A total of 41% (7) and 59% (10) were within and outside governmental control. Furthermore, a total of 19 facilitators were collectively identified, including ten known and nine suggested facilitators. Approximately 89% (17) and 11% (2) were within and outside governmental control. Critical obstacles and facilitators are further developed in the Sect. 4.

Table 2 Cost breakdown of Prosthetic Service Provider labour ($150/h) included in the schedule of allowable fixed expenses in the QALS procedure to provide prosthetic services and components to consumers fitted with bone-anchored prostheses

Treatment stage	Procedure phase	Items		Timeline (months)	Cost of PSP labour	
		ID	Intervention		h	$
Preoperative	P1	P1-A	Screening consultation	−3.0	2.0	300
Preoperative	P1	P1-B	Creation of passport	−2.0	0.5	75
Surgery	P2	P2-A	Consultation after surgeries	0.5	2.0	300
Surgery	P2	P2-B	Completion of passport	1.0	0.5	75
Rehabilitation	P3	P3-A	Pre-fitting of light limb	1.5	1.0	150
Rehabilitation	P3	P3-B	Fitting of light limb	2.0	4.0	600
Rehabilitation	P3	P3-C	Completion of passport	2.5	0.5	75
Rehabilitation	P4	P4-A	Pre-fitting of definitive limb	3.0	1.0	150
Rehabilitation	P4	P4-B	Fitting of definitive limb	3.5	10.0	1500
Rehabilitation	P4	P4-C	Completion of passport	4.0	0.5	75
Total fixed					22.0	3300

PSP Prosthetic Service Provider, *QALS* Queensland Artificial Limb Service

Table 3 Overview of initial and ongoing obstacles identified after implementation of formal procedures for provision of bone-anchored prostheses

	Governmental control	
	Within	Outside
Initial obstacles		
Estimation of PSPs' hours for preoperative, surgery and postoperative prosthetic care	x	
Review of QALS paradigm for allocation of advanced knee unit	x	
Absence of procedures for preoperative, surgery and postoperative care	x	
Difficulties to easily extract 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		x
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 in 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
Standardization 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

PSP Prosthetic Service Provider, *QALS* Queensland Artificial Limb Service, *BAP* bone-anchored prosthesis

Table 4 Overview of known and suggested facilitators to implementation identified after implementation of a formal procedure for provision of bone-anchored prostheses

	Governmental control	
	Within	Outside
Known facilitators		
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 the perspective of PSPs and consumers	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	
Negotiate regularly with suppliers of components	x	
Will from QALS management team to facilitate changes	x	
Understand rehabilitation and safety requirements		x
Suggested facilitators		
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

PSPs Prosthetic Service Providers, *AMPAT* Amputee Mobility Predictor Assessment Tool, *SF36* Short-Form 36, *Q-TFA* Questionnaire for Transfemoral Amputees, *QALS* Queensland Artificial Limb Service

4 Discussion

4.1 Key Results

This study showed that:

- the procedure developed between January 2011 and June 2015 included seven processes involving fixed expenses during treatment, and five processes regulating ongoing prosthetic care expenses;
- prosthetic care required 22 h of labor, corresponding to $3300 per patient, during rehabilitation. Prosthetists spend 64 and 36% of their time focusing on prosthetic care and other underlying activities, respectively;
- a stepwise process identified a list of initial and ongoing obstacles as well as known and suggested facilitators that were deemed within and outside governmental control.

4.2 Interpretations

4.2.1 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, the PSPs' scope of practice and activities were compliant with Australian competency standards for qualified prosthetists [62]. However, it is anticipated that prosthetists might become the 'gate keeper' for patients with a 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 the fixation part after a fall). In addition, they will more likely become the first point of care to prevent, diagnose, and refer for treatment at, for example, the initial signs of infection.

Another adjustment was the funding of a 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 the rehabilitation program, corresponding to stage 3 of the procedure. Built with basic components, this temporary prosthesis only provides a limited range of movement and restricted ambulation. Attempts to minimize

costs were made by encouraging PSPs to use a 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 the standards for allocation of prosthetic knee units is needed since consumers with a BAP must be fitted with microprocessor-controlled knees, mainly for safety reasons (e.g. loading profile, fall prevention) [20, 21, 31, 32, 58–61]. 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.

4.2.2 Manageable Obstacles

The 'acting' step revealed that the current number of processes remains an obstacle, within governmental control, to overcome. As presented in Fig. 2, the existing procedure relies essentially on PSPs to coordinate and document up to 12 processes per consumer during the first year. The underlying paperwork is time-consuming and burdensome. Therefore, efforts should be made to streamline systematic processes around the provision of expensive items (e.g. light and definitive limbs), while ensuring the responsibility of clinical stakeholders as well as 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 treatment with press-fit fixation for transfemoral amputations. This issue is resolving as particular rehabilitation programs for this case mix are becoming more established [8–11, 13, 16, 63–67]. Nonetheless, this has led to uncertainty in the relevance and timing of PSP involvement for preoperative, surgical, and postoperative prosthetic care. Unfortunately, a lack of specific rehabilitation programs is likely to remain ongoing and is likely to demand consistent attention in the upcoming years with the anticipated emergence of new fixations. These treatments might involve rehabilitation programs that are different from those currently available and, consequently, require different PSP involvement.

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

4.2.3 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 the involvement of PSPs, fitting of a light limb during rehabilitation, and the need for microprocessor-controlled knee units;
- use a document to track a patient's journey (e.g. passport of service) to contribute to patient empowerment and facilitate continuum of care, particularly for multidisciplinary services performed interstate;
- establishing systematic processes focusing on assessment, approval before reimbursement, and provision and reporting of expensive items [68].

4.3 Limitations

This procedure has now been implemented for over 2 years for 18 consumers. All participants had unilateral transfemoral amputation, and were mainly located in metropolitan areas in reasonable proximity to PSPs. Only a small number of dedicated PSPs and clinicians were involved.

4.4 Generalization

The overall 2-year duration of observation allowed us to consider a convenient cohort size of 16 participants, which might be considered sufficient given the limited number of patients accessing this type of treatment (e.g. eligibility, out-of-pocket costs). However, this sample size is slightly above the average of 14 participants in studies in the field of prosthetics [69]. Furthermore, the population could possibly be representative as it corresponded to 13 and 3.2% of the 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, and only one action research cycle was conducted.

Finally, one additional limitation to generalization is that this procedure was only a reflection of an Australian State organization focusing on prosthetic care. Treatment pathways for the provision of BAPs could differ between jurisdictions. For example, costs for BAPs fall mainly under the rim of rehabilitation providers and not PSPs in only some European countries. In the US, members of

active duty treated through a Department of Defence research protocol supported by FDA-approved Humanitarian Device Exemptions may apply for a waiver under the Supplemental Health Care Program process.

Together, 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, particularly its capacity to integrate more complex case mixes (e.g. transtibial, multilevel amputations), the geographical spread of consumers extending to rural areas with limited access to a PSP, and the increasing number of treatment sites in Australia and abroad, as the surgery becomes more routinely performed.

4.5 Future Studies

Clearly, there will be a need to further extend this procedure to accommodate future developments in BAP, including, but not limited to, the growing number of consumers, broadening of the case mix, changes to surgical procedures, emergence of multiple treatment centers, and constant developments of prosthetic components [59, 70–73]. The effects of these changes in the development, implementation, and evaluation of the 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. 6-year funding cycle) [74]. The satisfaction of PSPs will be of particular interest as the BAP could possibly lead to loss of income due to a reduction in socket manufacturing. Consequently, a cross-comparison of compensation provided by the QALS ($3300) will be needed to establish whether a BAP represents a loss, or comparable or increased revenues for PSPs.

Additional cross-sectional studies will focus on procedure performances in combination with the measure of impact of BAPs 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 in sick leave), and cost effectiveness of BAPs compared with socket prostheses (e.g. reuse of pre-existing components, cost comparison, cost per quality-adjusted life-year, incremental cost-effectiveness ratio), and other orthopedic devices (e.g. knee and hip implants) [5, 15, 17, 18, 20, 21, 30, 32, 35, 75–79].

Altogether, this new information will facilitate product development and effective adoption of a procedure for sustainable provision of BAPs [48, 80].

5 Conclusions

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

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Author Contributions LF contributed to the management of the whole study, including the design of the methods, collection of information, analysis and interpretation of the data, and writing of the manuscript. GM contributed to the development of the methods, analysis and interpretation of the data, and writing of the manuscript. TQ contributed to the collection of information and review of the manuscript. BB contributed to the management of the project, interpretation of the data, and review of the manuscript. DB contributed to the management of the project, collection of information, interpretation of the data, and writing of the manuscript.

Compliance with Ethical Standards

The study followed ethical guidelines from Queensland Health's Health Innovation, Investment and Research Office (HIIRO), responsible for consultation, development, and review of statewide research ethics and research governance policies. The University of the Sunshine Coast received funding from the 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 a consultant, by the University of the Sunshine Coast, to manage this research project, including collection, analysis, and reporting procedures, as well as cost data. He has also worked as a consultant for several organizations, on non-related educational programs and research projects, to work on recording of loading data, development of databases to record clinical outcomes, and drafting of grants and manuscripts. Gregory Merlo declares that he has no conflicts of interest. Tanya Quincey is a client service officer at the QALS and receives a salary from Metro-South Hospital and Health Service, Queensland Health. Brendan Burkett is a Professor at the University of the Sunshine Coast and managed the funding provided by the QALS. He receives a salary from the University of the Sunshine Coast. He was also the first Australian with transfemoral amputation fitted with Integral Leg Prosthesis (Orthodynamics, UK) fixation. Debra Berg is the Manager of the QALS and receives a salary from Metro-South Hospital and Health Service, Queensland Health.

Data availability statement All data generated or analyzed during this study are included in this published article. The QALS procedure for the provision of BAPs to Queensland consumers, generated during the current study, is available from the corresponding author on reasonable request. Generic information regarding QALS procedures is available at https://www.health.qld.gov.au/qals.

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