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Innovative technologies for reverse total shoulder arthroplasty in Australia: Market access challenges and implications for patients, decision-makers, and manufacturers

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ABSTRACT

Purpose: The success of reverse total shoulder arthroplasty (RTSA) has expanded its use for a broader range of shoulder indications worldwide. Evidence regarding the relative efficacy and long-term safety of medical technologies used in RTSA is subjected to rigorous assessment. Nonetheless, substantial challenges impede market access for innovative shoulder implant technologies for RTSA in Australia, resulting in delayed patient access.

Approach: This paper addresses the key challenges associated with generating evidence for the health technology assessments of innovative medical technologies for RTSA that are required for access to the Australian market. The transition to value-based care requires establishing a benchmarking reference that incorporates patient-reported outcome measures (PROMs) and combines revision outcomes with additional clinical outcomes to increase patient cohort sizes. Establishing the benchmark would require agreement on the outcome measures to be collected for each indication, and investment in reporting patient-reported outcomes for RTSA to the national orthopaedic registry.

Implications for practice: The need for increased flexibility in developing evidence for health technology assessment of RTSA medical technologies is required. Optimised approaches for benchmarking RTSA require extensive stakeholder discussions, including the agreement on evidence requirements and follow-up periods, selection of clinical outcomes, as well as pre-operative and post-operative PROMs as a value assessment.

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Reverse total shoulder arthroplasty; health technology assessment; market access

What is already known about this subject?

- Benchmarking algorithms that determine minimum sample sizes for RTSA have been adopted from total knee arthroplasty (TKA) and total hip arthroplasty (THA) (N = 250 patients at two years follow-up), despite the complexity and lower surgeon volume of surgery for RTSA.
- Revision rates and survivorship are the most frequent outcomes collected by registries.
- Reporting PROMs in shoulder arthroplasty clinical trials continues to increase. However, there is a lack of consistency in PROMS used in national registries worldwide, and PRO data is not used to support decision-making regarding shoulder implant reimbursement in Australia.

What does this study add?

- Highlights the challenges for evidence generation for RTSA
- PRO data collected using validated methods and published in peer-reviewed journals should be considered as supporting evidence, as it complements understanding of overall implant performance. However, a consensus is required on which PROMs to use and what will be acceptable for HTA.
- Potential solutions to overcome the challenges of evidence generation include reducing the sample size requirements and supplementing with PRO data. However, this should be achieved through collaborations between industry, local institutions, and patient organisations.

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Introduction

Reverse total shoulder arthroplasty (RTSA) is a safe, elective procedure with low overall morbidity [1]. In Australia, RTSA is the most common type of total shoulder replacement undertaken, accounting for 66.9% of all total shoulder procedures [2]. RTSA incidence in Australia increased from 3.1 per 100,000 in 2008 to 21.4 per 100,000 in 2020, reflecting the expanding surgical indications for RTSA [2]. The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) has the highest number of patients implanted with primary RTSAs out of the national and international arthroplasty registries [3].

The indications for RTSA have broadened to include rotator cuff tear deficient shoulders without arthritis, revision arthroplasty, proximal fractures and primary osteoarthritis (OA) [2,4]. Some shoulder arthroplasties may require implant revision. The reasons for failure are multifactorial, generally caused by an intrinsic factor or a combination of factors associated with the soft tissue, bone, or implant [5]. Common types of failure, including loosening, bone loss, or instability, can be diagnosed using standard radiographs [6].

Despite the therapeutic benefits that novel prostheses for RTSA may provide, the limited clinical and patient-reported outcome data at the time of launch pose a significant obstacle to achieving successful market access and device reimbursement in Australia. Market access allows organisations to understand how stakeholders define value and where their portfolio is strong and weak worldwide, ensuring companies improve design and clinical performance of their products.

Device reimbursement in Australia comprises different Health Technology Assessment (HTA) processes and agencies, multiple pathways and variable levels of clinical and economic evidence requirements [7,8]. The Prostheses List (PL) is a list of technologies for which private health insurers are required to pay a specific benefit as outlined in Division 72 of the Private Health Insurance Act [9]. To be included on the Prostheses List, a sponsor applicant must demonstrate substantial clinical equivalence to an already listed device [10]. When the device is considered high risk, requires long-term durability or is novel in design, an applicant must provide clinical evidence establishing safety and efficacy with at least two years of follow-up [10]. Applications are assessed by practicing clinicians [10]. However, this assessment process and recommendations are not publicly documented and remain less than transparent, with brief reasons provided to sponsors for approval or rejection.

Table 1. Shoulder arthroplasty outcomes [25].

Core Outcomes
• Mortality
• Quality of life
• PROMs
• Infection
• Revision surgery
• Major adverse events
• Return to work/activity/sports
• Component failure
• Dislocations
• Length of hospital stay

Generating clinical evidence for regulation, value assessment, and market access of novel shoulder prostheses for RTSA is difficult for manufacturers due to multiple indications, divergent clinical pathways, and differences in resource use and cost in various countries [11]. Therefore, it is critical to comprehensively review the potential challenges in the market access of shoulder prostheses to stimulate discussions on the appropriate solutions and address them for unlocking the clinical outcomes and improving the quality of life for Australian patients.

In this paper, we focused on the challenges faced by manufacturers of shoulder prostheses for RTSA in aspects of HTA evidence assessment for market access. The article discusses the implications of future efforts and strategies needed to accelerate clinical evidence generation, enable the use of real-world data and evidence, to enable timely patient access to innovative technologies for RTSA.

Methods

We reviewed literature and articles on RTSA, orthopaedic registry data, PROMs in shoulder arthroplasty, and RTSA clinical evidence on Ovid MEDLINE database, government websites, the national orthopaedic registry and grey literature. The identified challenges were grouped into two main topics: Data challenges and Market access and Reimbursement challenges.

Results

Data challenges

Methodological Quality, Clinical Outcome, and Patient-Reported Outcomes

The criterion for a successful outcome after shoulder arthroplasty remains unclear [12]. To include the

patient's perspective, a broader definition of a satisfactory outcome is necessary [13,14]. Despite the fact that the elective shoulder surgery population represents a significant healthcare burden [15], no research has demonstrated the need to standardise outcome measures or enhance study-quality criteria. There is a compelling need to standardise and assess healthcare outcomes due to the burden of shoulder surgery [16].

Inconsistency and a lack of standardised outcome selection and assessment appear to be common across medical fields [17]. Due to the inconsistent selection of outcomes in clinical trials and wide range of PRO tools available for shoulder arthroplasty, it is challenging to standardize outcome and tools for clinical trials [18]. A review of registered clinical trials for shoulder arthroplasty discovered a lack of consistency in terms of outcomes and PRO tools [18].

The absence of standardisation limits data synthesis in systematic reviews, as results are restricted to studies that have used the same tools to report selected outcomes [18]. Similarly, issues in methodological quality are prevalent in shoulder replacement studies [19], exacerbate the difficulties in evaluating data from various studies to aid decision-making [20].

Systematic literature reviews are unable to provide accurate recommendations for elective shoulder surgeries due to a lack of standardised outcome selection and low methodological quality of included studies [21,22]. The creation of core outcome results, methodology and reporting criteria has been suggested [23,24]. A core outcome result approach, as shown in Table 1, that specifies the range of outcomes to be measured in RTSA trials could address these challenges [18].

Orthopaedic Registry Data

With the rising prevalence of RTSA, attempts to monitor and enhance the efficiency and effectiveness of the surgical procedure are essential. Orthopaedic registries are used to monitor real-world safety and efficacy, quality of care, surgeon performance, and determine cost-effectiveness of procedures [26]. Registries provide long-term data on implant performance, the influence of surgeon volume in revision rates and patient-reported outcomes [27].

The AOANJRR, like other national registries, reports prosthesis performance using revision rates or formal survival analyses as outcomes [13]. National registries provide revision rate and survival as the key outcomes, with less clinical outcome and PRO reported [3]. Clinical and radiological outcomes are often reported in local databases [28].

However, it has been established that the revision rate alone does not to adequately indicate the success of the surgery [13]. The registry data does not provide information on length of stay, patient-reported outcomes, or radiological outcomes. Arthroscopy and procedures other than the replacement, removal, or insertion of a prosthetic component is not reported. These procedures may have been performed without being reported as additional surgeries [29].

The majority of failure-related data pertaining to the implant, patient, or surgery are not reported in orthopaedic registries [30]. A degree of heterogeneity is likely to exist among patients with a primary diagnosis of OA [29]. However, the AOANJRR does not report the pattern or severity of OA, but reports details of glenoid morphology [29].

PROMS collected by Orthopaedic Registries

PROMs are widely used in various healthcare settings [31] and are frequently required to assess the quality of care. Globally, registries are broadening data collection to include PROMs which provide an important patient perspective on surgical outcomes and improve clinical decision-making processes [32].

Improvement in PRO after RTSA is determined by assessing pre-operative and post-operative follow-up scores. PROMS are not a mandatory outcome in orthopaedic registries [30].

Depending on the surgeon's preference and geography, different PROMs are used for shoulder arthroplasty. An evaluation of seven national orthopaedic registries (Australia, the United Kingdom (UK), Denmark, the Netherlands, New Zealand, Norway, and Sweden) indicated that the use of PROMs was inconsistent and reported data was incomplete [30].

The International Society of Arthroplasty Registries issued guidance on PROMs instrument selection, recommending that the instrument or specific PROMs questions be developed in collaboration with the relevant patient group and measurement properties specific to arthroplasty patients [33].

Orthopaedic registries differ in the type of PRO instrument used, as well as the frequency and timing of the follow-up, making comparison difficult [30].

The Oxford Shoulder Score (OSS) [34] is used in the orthopaedic registries in the UK, New Zealand, and Norway, while the Western Ontario Osteoarthritis of the Shoulder (WOOS) [35] is used in Sweden and Denmark. The outcomes, measurements, and stratification included in the Australian orthopaedic registry and international orthopaedic registries are summarised in Table 2.

Limitations of Orthopaedic Registry PROMs Data

A comparison of global orthopaedic registries would enable the outcomes of different implants for RTSA to be compared. However, the orthopaedic registries data cannot be compared due to considerable discrepancies in reported data, definitions of failure and loosening, and PROM tools [37–39]. There are also discrepancies in how surgeries are characterised, and where available, information on surgery by disease indication is not systematically reported, reducing the ability to merge registry data [38], for procedures like RTSA.

In comparison to knees and hips, a relatively smaller number of RTSA are performed annually [40].

Over a 12-month period, the AOANJRR collected PROMs data as part of a pilot for 52.3% of primary hip surgeries (N = 6273), 53.6% of primary knee surgeries (N = 9770) and 38.6% of primary shoulder surgeries (N = 613) [41,42]. PROMS (EQ-5D and OSS) were collected for primary RTSA for OA diagnosis and rotator cuff arthropathy [41]. There was inadequate data to report on the variance in PROMs data pre- and post-surgery for primary RTSA [41]. Patients undergoing shoulder arthroplasty are generally not included in a pre-admission clinic cohort, so several participating sites in the pilot were unable to enrol them [41].

The purpose PROMS pilot was to determine the viability of AOANJRR establishing national data collecting for patients undergoing joint replacement surgery [41]. A list of recommendations was produced on how to optimise national implementation of PROMS data collection [41]. AOANJRR recommended that increased communication with all surgeons, particularly shoulder surgeons, was required to ensure the maximum number of patients are registered both in and out of pre-admission clinics [41].

Market access and Reimbursement challenges

Benchmarking

National arthroplasty registries provide clinical and safety information for surgeons and patients through annual reports, identifying outlier implants, and implant benchmarking. Benchmarking is a systematic process that determines if an implant meets specified performance levels [43,44].

National benchmarking efforts are performed by three groups globally, (1) Prostheses List Advisory Committee (PLAC) in Australia [45], (2) Orthopaedic Data Evaluation Panel (ODEP) in the UK [46], and Netherlands Orthopaedic Association Classification of Orthopaedic Implants in the Netherlands [47].

The International Prosthesis Benchmarking Working Group (IPBWG) was established to review current systems and develop a global system proposal to evaluate and benchmark arthroplasty prostheses performance [48]. The IPBWG proposed protocol describes benchmarking based only on cases performed for a diagnosis of OA and a clinical endpoint of all-cause revision [48]. The statistical subcommittee of the IPBWG analysed AOANJRR data [49] and established that poor implant performance at an early benchmark of two years is predictive of poor performance at 10 years [48].

In Australia, PLAC has used this benchmark for novel shoulder prostheses [48], despite the technical difficulty and lower surgical volume of TSA compared to TKA and THA [50], as well as the primary diagnosis of RTSA being OA, rotator cuff insufficiency, and fracture. Revision rates vary based on diagnosis, with some diagnoses associated with increased revision rates (e.g., fractures, tumours). The performance of shoulder prostheses is potentially affected by the relative proportion of procedures undertaken by surgeons for different diagnoses [48]. TKA and THA have a considerably higher volume of procedures than RTSA.

In addition, the endpoint of revision surgery only focuses on survival and does not capture poor functional results. The criteria to measure surgical success needs to be expanded to included measuring outcomes such as pain relief, restoration of function and flexibility, and the improvement in patients' quality of life [32].

There is continuing debate over whether to group similar prostheses together for larger numbers and statistical significance or to split prostheses into smaller groups for analysis, which spreads out the time to achieve statistical significance [51]. The main challenge of the benchmark for shoulder technologies is that the assessment of impact of an innovative prosthesis can only be determined once 250 surgeries with two years follow-up are performed [51].

The two-year follow-up requirement is most likely based from studies on hip and knee arthroplasty, which indicate patients continue to recover two years after surgery [52], rather than research on shoulder arthroplasty recovery [53].

Lower surgeon operating volume compared to knee and Hip arthroplasty

The effect of surgeon operating volume on patient outcomes is well documented [54]. Modern shoulder arthroplasty is continually evolving, and surgeon operating volumes are less than lower limb arthroplasty [29]. A low surgeon operating volume in RTSA (<10/year) is

Table 2. Outcomes, measures, and stratification reported by regional/national registries [36,38].

Country/ Region	Main outcome	Other Outcomes	Revision measure	Revision stratified by:	Cause of Revision stratified by:	Revision stratified by indication AND procedure type
Australia	Revision	No	Revisions/100 component years (95% CI); cumulative revision probability (95% CI) (survival curve)	Age, sex, indication (all), procedure type, prosthesis brand, fixation, glenoid type, and glenoid design	Yes, indication, procedure type	Yes (+by prosthesis brand)
New Zealand	Revision	OSS (6 months postoperatively, then every 5 years)	Revisions/100 component years (95% CI); survival (survival curve)	Age, sex, procedure type, prosthesis brand, glenoid fixation, surgeon annual workload, OSS score at 6 months	Yes	No
UK	Revision	Mortality, OSS (baseline and 6 months postoperatively)	Cumulative revision probability (survival curve)	Indication (elective-acute trauma), procedure type	Yes, procedure type	Yes
Sweden	Revision	WOOS, EQ5D (1, 5 and 10 years postoperatively)	Cumulative revision probability (95% CI) (survival curve)	Indication (all), procedure type	No	Yes
Denmark	Revision	Reoperation rate, WOOS (1 year postoperatively)	n (%), survival (95% CI)	Indication (OA-acute trauma-fracture > 14 days), procedure type, hospital	Yes, procedure type	Yes
Norway	Revision	OSS, EQ-5D	n	No	Yes, procedure type	No
California, USA	Revision	Deep infection, DVT, PE, 30- and 90-day mortality	n (%)	Indication (elective-acute trauma)	Yes, indication (elective-acute trauma), procedure type	Yes
Emilia-Romagna, Italy	Revision	No	Survival (95% CI) (survival curve)	Procedure type	Yes, procedure type	No

Abbreviations: OA = osteoarthritis; CI = confidence interval; WOOS = Western Ontario Osteoarthritis of the Shoulder; OSS = Oxford Shoulder Score.

associated with higher all-cause revision rates for OA in the early post-operative period and the follow-up for cuff arthropathy [29].

Revision rates for the complications of instability/dislocation and fractures following RTSA performed as treatment for OA, are higher when the surgery has been performed by a low volume surgeon (<10/year) compared to surgeons with higher operative volumes (10–20/year and >20/year) [29]. However, revision for loosening and cuff arthropathy was not found to be affected by surgeon operating volume [29]. Although there is a significant increase in the volume of shoulder arthroplasties performed in recent years, more than 78% of surgeons undertake fewer than 10 procedures per year [29].

This is a challenge, as investigations of new implants could be reserved for high-volume centres only and limit the access of surgeons and patients at lower-volume centres.

Discussion

Earlier access to innovate technologies for RTSA lead to better outcomes for patients that include improved quality of life, as well as decreasing healthcare costs through reducing inefficiencies and reoperations. Over the last decade, the role of RTSA has expanded for both primary and revision indications in the shoulder [16].

The MedTech industry responds to evolving surgical techniques, thus is a rapidly developing and dynamic sector. The proliferation of emerging digital technologies will affect the medical device market and the design of implant registries [26]. Data linkage will enable efficient use of data as medical devices, processes, and patient data get connected [26].

The uncertainties in comparative effectiveness and durability of clinical benefits remain the biggest challenge for the robust HTA and economic analysis of shoulder protheses. Research has strongly advocated improving the quality of clinical evidence, which is crucial to assure HTA bodies and payers of the clinical advantages of modern shoulder prostheses [55,56].

Evidence generation

Despite the challenges in generating comprehensive evidence, some practical solutions for manufacturers include implementing coverage evidence development (CED) schemes [57]. CED is a type of risk-sharing agreement based on performance that allows the entry of innovative health technologies into a healthcare system [58]. CED schemes offer conditional coverage and payment programs in which temporary or interim financing and access to innovative medical technologies are offered on the condition that data are collected concurrently to prove clinical and economic value [59].

In Australia, CED schemes are referred to as 'interim funding schemes', however they are not currently utilised for medical device technologies [60]. CED schemes assist in addressing uncertainties around costs and outcomes by generating evidence on the effectiveness and efficiency of new medical technologies [61]. Japan and South Korea recommended the use of CED to overcome the challenge of a lack of robust clinical data in the early phases of the adoption of a new medical technology [61]. The use of CED data from countries in Asia-Pacific can support reimbursement applications in Australia.

The Australian Department of Health and Aged Care (DoHAC) can actively engage and participate in collaboratively designing and implementing CED schemes with multiple stakeholders to enable patients to benefit by improved access to innovative medical technologies [61].

A HTA process that combines technology reimbursement with evidence generation is efficient [62]. There is a need to modify the HTA pathways to permit early entry channels for novel technologies into hospitals [62]. The DoHAC should prioritize avenues for manufacturers to utilize CED schemes in Australia to generate real-world evidence that demonstrates shoulder prostheses safety, efficacy, and value.

PL reimbursement process

Set benchmarks specifically for shoulder prosthesis

The current Prosthesis List Guide to Listing document does not have a separate category for shoulders as it does for knees and hips, instead shoulders are included in the 'Upper limb' subcategory of the 'Specialist Orthopaedic' category, which also includes a subcategory for 'Skeletal reconstruction' devices [45]. Creating a separate category for Shoulder prostheses and expanding data requirements to include medium and long-term efficacy can alleviate this challenge.

As the treated population for RTSA is small compared to TKA and THA, the requirement of 250 patient surgeries with a two-year follow-up result in delayed patient access to novel shoulder prosthesis, due to the lower surgical volume and complexity of RTSA compared to TKA and THA.

An appropriate alternative could be to use a lower number of surgeries, such as 150 surgeries at two-year follow-up for clinical outcomes, in addition to PROMS data for 100 patients at one-year follow-up. A study demonstrated that shoulder arthroplasty investigations

may not require the minimum two-year clinical follow-up, as PROs and range of motion scores plateaued at one year postoperatively without further complications [53]. For benchmarking purposes, further research is required to determine the appropriate number of surgeries for safety and clinical outcomes for the various indications for shoulder arthroplasty.

As evidence generation is a challenge for lower volume upper extremity procedures, the HTA pathways will have to consider patient metrics data of quality, efficacy, and safety to underpin equitable access to novel technologies for patients undergoing RTSA. Clear guidelines outlining the basis for evidence requirements and the follow-up period are required for shoulder prosthesis systems, individual components as well as computer and robotic-assisted solutions.

Patient-advocacy involvement in HTA

Patient-reported outcomes may be utilised for clinical research, reimbursement, and benchmarking for patient comparison with a matched population cohort [63]. Insights into the patient experience regarding outcomes such as pain relief or patient functioning should be incorporated into HTA appropriately as this may affect reimbursement [64].

Using PROMs can address the shortcomings of only using revision as an endpoint by expanding beyond survival and measuring patient-relevant outcomes such as relief of pain, restoration of function, and quality of life [32].

Manufacturers should collaborate with the AOANJRR, shoulder surgeons, and patient-advocacy groups to ensure patients waiting for RTSA are enrolled in pre-admission clinics and promote the collection of PRO data for the broader value story for novel shoulder prostheses introduced to the market [65].

PROMs data can provide value for differentiation versus competitors, influencing surgeon decision making. PROMs can be integral to broader market access if tied to a patient-centric value proposition [66]. However, the PLAC would have to provide clear guidelines and outline the data requirements and process of how PROMS (EQ-5D, OSS and WOOS) can be incorporated in their assessments [67].

Understanding the importance of outcomes and their related costs can benefit all stakeholders and help achieve sustainability of the healthcare system by directing resources from low-value care to high-value care [68].

Strategies to improve market assess

The PLAC should increase the use of real-world evidence during decision-making. The PLAC should define a framework for the decision-making process for shoulder prosthesis systems and their components and provide formal documentation of decision-making processes when an application has been rejected to sponsor applicants. This transparency will allow manufacturers to be aware of evidence requirements and the criteria on which a decision was made and be informed on what clinical or economic evidence is required.

Limitations

Our review of the literature identified key challenges faced in the market access of novel shoulder prostheses for RTSA in Australia. However, the DoHAC is conducting PL reforms targeted at lowering medical device prices, which include regrouping products on the PL to better align devices with comparable intended use or health outcomes [69]. The DoHAC will implement these reforms in stages over a four-year period beginning in 2022, with all reforms to be implemented by 2025 [69]. It is yet to be determined how the reforms will impact the PL listing pathway and evidence requirements for shoulder prostheses. Future research should evaluate how these reforms will impact access to shoulder prosthesis systems, components, computer, and robotic-assisted solutions in Australia.

Conclusion

The PL process should allow flexibility in the use of real-world evidence to demonstrate the value of innovative RTSA prostheses while reducing the burden of collecting clinical data are required [70]. A HTA pathway for shoulder prostheses with different evidence requirements from knee and hip procedures is urgently required. The PLAC should set benchmark requirements that are aligned to the surgical volume and complexity of shoulder arthroplasty.

Collaborations between industry, local institutions, and patient organisations to design evidence generation processes provide an opportunity to efficiently generate the evidence required to accelerate patient access to novel technologies.

Disclosure statement

Dr Mutsa Gumbie, Michelle Costa and Michael Erb are employed by Johnson & Johnson MedTech. Dr Gnanadarsha Dissanayake has no potential conflict of interest to declare.

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