Towards a safe and sustainable orthotic and prosthetic workforce

SUBMISSION FROM:
The Australian Orthotic Prosthetic Association Inc., representing the Australian Orthotic and Prosthetic profession

TO THE PRACTITIONER REGULATION SUBCOMMITTEE:
For inclusion in the National Registration and Accreditation Scheme
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1. FORWARD

We are pleased to present this submission which outlines the case for inclusion of Orthotist/Prosthetists in the single, National Registration and Accreditation Scheme (NRAS) for health professionals, supporting the goals of the 2008 Intergovernmental Agreement, to promote public safety. This submission has been prepared by The Australian Orthotic Prosthetic Association (AOPA) Inc., which is the peak professional body for Orthotist/Prosthetists. The preparation of this submission has included consultation with members, who represent 75% of the profession nationally, as well as other industry leaders, such as the National Centre for Prosthetics and Orthotics (NCPO) at La Trobe University and the International Society for Prosthetics and Orthotics (ISPO) Australian National Member Society.

The Australian healthcare system is under constant pressure to reduce the burden of illness, injury and disability on the community through the provision of high quality healthcare. The aging population and increasing prevalence of chronic disabling conditions strains the current allied health workforce. The single NRAS has been established to ensure the public health interest is safe guarded during a time of rising demands on the healthcare system. This system promotes transparency and accountability of the health professions, and places the public interest clearly over profession self-interest.

This submission from The AOPA Inc., for inclusion in the NRAS, is driven by three key strategic directions:

- guaranteeing public safety through the provision of quality healthcare by ensuring the community can readily identify appropriately skilled and qualified Orthotist/Prosthetists
- ensuring consistency and confidence in deploying the orthotic and prosthetic workforce and removing impediments to a flexible, mobile workforce whilst maintaining safety and quality for the public
- promoting equity of access to orthotic and prosthetic services which meet appropriate safety and quality standards

In Australia, Orthotist/Prosthetists are dynamic members of multidisciplinary teams and work within a diverse range of settings. The Orthotic and Prosthetic practitioner works across the entire age spectrum and is an integral team member in the provision of health care to some of Australia’s most vulnerable and disadvantaged groups. This context requires the Australian Orthotist/Prosthetist to be qualified and clinically competent in order to provide orthotic and prosthetic solutions for a diverse range of presentations. The provision of inadequate services compromises individual outcomes, decreases public trust, and has potential for life changing effects, such as major injuries, within an already disadvantaged sector of the community.

Voluntary self-regulation, government legislation and other regulatory mechanisms fall well short of protecting the public interest and safety in Australia. Whilst unregulated, the necessary quality assurance standards for orthotic and prosthetic practice are not guaranteed and the public interest is not protected.

The orthotic and prosthetic profession has a strong history of advancement in Australia and can demonstrate a clear and established body of teachable knowledge, and standards of practice and competencies, which equip the practitioner to
provide quality services for people with disabilities. Inclusion in the NRAS will provide the necessary framework to monitor and manage the risks to public safety that are inherent in any health profession, but also those specific to orthotics and prosthetics.

The Australian orthotic and prosthetic profession is focused on promoting independence and the achievement of mobility goals for people with disabilities and recognises that these services must be provided in the safest of frameworks. For the public interest, the profession is committed to moving forward towards national registration, and is well placed to operate within the new framework.

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2. CONTEXT

The future of the Australian healthcare workforce

“Cohesive action is required among the health, education, vocational training and regulatory sectors to promote an Australian health workforce that is knowledgeable, skilled, competent, engaged in lifelong learning and distributed to optimise equitable health outcomes”1.

The Australian Productivity Commission’s report ‘Australia’s Health Workforce’ was released in 2006. It highlighted and recommended the need for a single national registration board for health professionals to promote public safety and ensure a sustainable, mobile and flexible workforce. The 2008 Intergovernmental Agreement (IGA) for a National Registration and Accreditation Scheme for Health Professionals (NRAS) was borne from this recommendation. This forms a key part of the most ambitious reforms to the health professions since the mid-19th century.

Registration is the process of legally recognising practitioner’s qualifications, coupled with experience, character and fitness to practice. This provides the public with assurances of the minimum standards of service and establishes quality and safety standards. These reforms are necessary to assist the health workforce manage the increasing prevalence of chronic conditions associated with Australia’s aging population. Public safety is the primary focus of the IGA, however the agreement illustrates its link with workforce issues. The following objectives within the legislation highlight this relationship:

- To provide public protection by ensuring health professionals are suitably trained and qualified to practice in a competent and ethical manner
- To promote a flexible, responsive, sustainable and mobile health workforce, including the rigorous and responsive assessment of overseas-trained practitioners
- To have regard to the public interest in promoting access to health services

The scheme began on 1 July 2010 with the inclusion of ten health professions that were previously registered in all jurisdictions. These were: Optometry, Nursing and Midwifery, Chiropractic care, Pharmacy, Dental care (dentists, dental hygienists, dental prosthetists and dental therapists), Medicine, Psychology, Osteopathy and Podiatry.

The IGA has provision for the inclusion of additional health profession groups. Further inclusions will be based on six benchmarking criteria, as established in 1995 by the Australian Health Minister’s Advisory Council. These criteria ensure that the potential for inclusion in the scheme is assessed on a national benefit-cost framework and a case-by-case basis, accounting for alternatives such as self-regulation, credentialing and delegation.

This submission outlines the case for the inclusion of Orthotist/Prosthetists in the NRAS, in order to strive for the highest level of health and safety for the clients this profession services.

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1 Australian Health Minister’s Conference, 2004, p.15
3. STRATEGIC DIRECTIONS

Promoting a safe, flexible and sustainable Australian healthcare workforce

“While licensure can improve competency standards, professional validation, a defined scope of practice, reduction of fraud and abuse, a greater voice in state policy, professional accountability, increased quality, and improved economics, the overriding reason for states to license the orthotic and prosthetic profession is consumer protection”.

The orthotic and prosthetic profession’s submission for inclusion in the single NRAS is based on three key strategic directions: (1) guaranteeing the quality of healthcare by ensuring the community can readily identify appropriately skilled and qualified Orthotist/Prosthetists; (2) ensuring consistency and confidence in deploying the orthotic and prosthetic workforce and removing impediments to a flexible, mobile workforce whilst maintaining safety and quality; and (3) ensuring equity of access to services which meet appropriate safety and quality standards within a flexible healthcare setting.

Australia’s health workforce is credited with providing the Australian public with one of the longest life expectancies and lowest incidence of chronic disease. The aging population and the changing face of health from acute to long-term chronic conditions places strain on the health system and the professionals at the community interface.

Professional regulation aims to provide the public with safety and protection when accessing health care. Further to this, it develops trust between the individual and their healthcare provider, and between the community and the health services they access. Professional regulation provides the community and health consumer with confidence in the service quality and sustainability of their healthcare system.

This submission argues that applying the single NRAS to the profession of orthotics and prosthetics will achieve the following objectives:

- **Promote public safety** by ensuring the Australian community can readily identify appropriately skilled and qualified Orthotist/Prosthetists
- **Support workforce mobility** by removing impediments to a flexible, mobile orthotics and prosthetics workforce whilst maintaining safety and quality
- **Promoting equity of access** by ensuring all orthotic and prosthetic services meet appropriate safety and quality standards within a flexible healthcare setting.

Ensuring the Australian community can readily identify appropriately skilled and qualified Orthotist/Prosthetists

Orthotist/Prosthetists are allied health practitioners who work in an autonomous manner to provide clinical and technical orthotic and prosthetic care. The profession promotes independence and the achievement of individual mobility goals through the provision of prostheses and orthoses.

Orthotist/Prosthetists provide clinical services into a variety of settings, such as; public and private hospitals, both as inpatient and outpatient services, rehabilitation centres, non-government organisations, aged care

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2 AAOP, 2010
facilities, community-based organisations, schools with special needs programs, respite centres, nursing homes and private practice. The Australian Orthotist/Prosthetist addresses equipment needs across the entire age spectrum and range of physical needs.

“One of the most important components of rehabilitation and support services is assistive devices which often provide the first step to ensure that people with disabilities are equal members of society. Among assistive devices, prostheses and orthoses are required by the majority of people with physical disabilities”

The orthotic and prosthetic profession is inextricably linked to other health services, in which intervention supports other professions to deliver treatment plans. Therefore, Orthotist/Prosthetists are key members of multidisciplinary teams providing services to people with chronic disabilities, neuromuscular conditions and mobility impairments. The nature of chronic disability demands the practitioner establish a long-term and trusting relationship with their clients, who require mobility devices for the rest of their life.

Orthotist/Prosthetists provide services to some of Australia’s most disadvantaged population. This client group relies on their treating professional to have high level clinical skills coupled with sound technical knowledge. When orthotic and prosthetic services are not provided in a professional and competent manner, the health and safety of an already disadvantaged section of the public is compromised, with a very real risk of injury and fatality.

Currently, it is the publics’ responsibility to identify a qualified and competent professional. Those who require orthotic and prosthetic services are most often from socio-economically disadvantaged groups. This sector of the community is already marginalised by their disability and health needs, making the additional responsibility of identifying competent clinicians unacceptable. The Australian government in conjunction with The AOPA Inc. has a responsibility to assist people with disabilities to access appropriate and safe health services through the regulation of the orthotic and prosthetic profession.

Professional regulation will establish clear qualification and competency standards for the provision of orthotic and prosthetic care in Australia. The restriction of professional title will enhance public safety, as it will limit the practice of unqualified individuals. The development of a national board will provide the public with an impartial and transparent process for raising concerns regarding the quality of care they have received from Australian Orthotist/Prosthetists.

Removing impediments to a flexible, mobile orthotic and prosthetic workforce

The Australian orthotic and prosthetic profession is a relatively mobile workforce however it is disproportionately represented around the major education facility, located in Melbourne. Many interstate and rural employers have difficulty recruiting and retaining staff. One of the current barriers to workforce recruitment is the lack of equity in the role and status of Orthotist/Prosthetists between states.

Nationally, there is variation in the clinical role of the Orthotist/Prosthetist. This creates inequality in the provision of services to the public, with some areas receiving integrated multidisciplinary management, and others accessing isolated orthotic and prosthetic professionals. This asymmetry in professional role is a
barrier to recruiting new graduates and senior staff, who prefer to working in advanced centres with a strong clinical focus. The employment issue compounds the inequality in service provision, with employers struggling to locate qualified professionals, often resorting to the employment of unqualified individuals.

Establishing consistent registration guidelines, with qualifications and competence levels for Orthotist/Prosthetists benchmarked nationally, will ensure that all employers are recruiting appropriately qualified and skilled staff. Registration will remove impediments to a flexible workforce. It will ensure the role of the Orthotist/Prosthetist is defined nationally, supporting the recruitment of appropriately trained international practitioners. Further to this, a reduction in the variation of the Orthotist/Prosthetist role nationally will remove barriers to workforce mobility and address the current workforce shortage.

As the orthotic and prosthetic workforce is small, it will benefit from improved integration with other health professions through professional registration. The NRAS will allow the collection of national workforce data which will support health workforce planning, and a national approach to meeting retention challenges.

Ensuring equity of access to orthotic and prosthetic services which meet appropriate safety and quality standards

The Orthotist/Prosthetist is an integral part of the provision of health services in a multidisciplinary framework. Health professionals who remain outside of the registration ‘net’ pose a continued, unmanaged risk to the quality of multidisciplinary client encounters.

“To provide for the protection of the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered”.

Members of the public who use orthotic and prosthetic services have a right to equity in access. This refers to equity in accessibility, but also service quality. The public should not be disadvantaged in the quality of orthotic and prosthetic services they receive due to national workforce issues, such as recruitment and retention.

The public requires a guarantee that their practitioner is appropriately trained and competent and is able to enact their skill within the health setting alongside other allied health professionals. Regulation of Orthotist/Prosthetists will ensure the practitioner role is similar across states, providing the public with a safe and equitable service.

“In order to assure a safe and high-quality experience for patients across the spectrum of their encounters with health professionals, we need to ensure proportionate arrangements for all the professions involved. There can be no weak links in the chain of care”.

If unregistered health professionals continue to work within the community and public sector, outside of quality assurance processes, they will be the weakest link of a multidisciplinary team. One weak link undermines the intentions of the IGA’s goal to protect the public interest through meeting the five objectives of the NRAS. From the client interest and safety perspective, improvements will not have occurred in a holistic manner whilst a section of the healthcare team remains outside of the ‘net’ of safety.

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4 Queensland Government, 2008
5 Secretary of State for Health UK, 2007, p.18
4. RESPONSES TO THE AHMAC AGREEMENT CRITERIA

4.1 Criterion One

Health Ministers to regulate the orthotic and prosthetic profession

The orthotic and prosthetic profession has seen dramatic change over the last 30 years. Previously a technical based occupation; there is a history of sitting outside the health professions and the definition of allied health. Due to changes in the provision of health services, population health needs and a team orientated allied health education model, Orthotist/Prosthetists are now regarded as integral members of the allied health team. With almost two decades of education at the Bachelor Degree level, the orthotic and prosthetic profession has shifted to a minimum education standard of Masters.

The dilemma facing allied health professionals in Australia is the large variations in allied health services in terms of workforce tracking, collective action for wage, working conditions, registration parity and/or educational opportunities and standards.\(^6\)

The extensive SARRAH report defines allied health professionals as “tertiary qualified health professionals who apply their skills to restore optimal physical, sensory, psychological, cognitive and social function . . . who are ‘allied’ or aligned to each other and their clients”. Only 14 of the 49 identified allied health professions from the SARRAH survey were included in the final workforce definition, with Orthotist/Prosthetists included. Further to this, the orthotic and prosthetic profession is a current and contributing member of the Allied Health Professionals Association (AHPA).

“Australia’s health workforce fulfills one of the most important roles in our country, that of providing effective, safe, quality care that improves the health and well-being of the Australian community.”\(^7\)

Orthotist/Prosthetists are employed in a variety of settings, including public and private facilities. They may be an integral part of an acute team, such as burns management, or a chronic disability multidisciplinary team, such as diabetic high risk foot management. The relationship between the Orthotist/Prosthetist and the client is often a permanent, long-term one due to the ongoing needs of people with chronic and permanent disabilities, such as the amputee population. Regardless of the clinical environment the Orthotist/Prosthetist will invariably be part of a multidisciplinary team, even if indirectly, as the majority of orthotic and prosthetic clients access other health professions and services.

The Minister for Health and Aging has current portfolio responsibilities including; hospitals, private health insurance and National Health Priorities. The orthotic and prosthetic profession sits within these areas of responsibility, and more importantly is a key health professional group in addressing the National Health Priority Areas (NHPA).

The Australian Department of Health and Aging defines its NHPA as: cancer control, injury prevention and control, cardiovascular health, diabetes mellitus, mental health, asthma, and arthritis and musculoskeletal

\(^6\) Turnbull, et.al, 2009

\(^7\) Lowe, et.al, 2007, p.5

\(^8\) Australian Health Ministers Conference, 2004
conditions. This includes the National Chronic Disease Strategy, which focuses on the management and prevention of musculoskeletal conditions and Diabetes Mellitus, in which Orthotist/Prosthetists play a significant role.

Conclusion
As an important allied health team member, employed within a variety of health settings, the regulation responsibility of Orthotist/Prosthetists falls directly within the domain of the Australian Health Minister.

4.2 Criterion Two

Risk of significant harm to the public

Orthotist/Prosthetists provide both a clinical and consultation service, coupled with the provision of a product, or equipment. The client group accessing these services rely on their treating professional having highly developed clinical skills and sound technical knowledge. When orthotic and prosthetic services are not provided in a professional and competent manner, the health and safety of an already disadvantaged section of the public is compromised, with a very real risk of injury and fatality.

“Prosthetics is unique among health professions because it is a co-primary product and service profession”.

Both the client and practitioner are exposed to a variety of risks related to the orthotic and prosthetic profession. These include clinical decision making and technical risks, such as exposure to materials and the integrity of the ‘product’. The nature of the service provided is often ambulatory, such as the prescription and fitting of lower limb prostheses and orthoses to enable walking. This is a high risk area within the hospital and community setting. Further to the provision of ambulatory services, the Orthotist/Prosthetist works in other high risk areas, including:

- Lower limb orthotic management to promote ulcer healing and control diabetic foot complications
- Lower limb orthotic management to support and protect body segments which have sustained injury, such as tendon or ligament damage

9 Billey, 2009, p 7
• Fracture management, such as the immobilisation of body segments to promote healing, allow weight-bearing, and support surgical procedures
• Upper-limb prosthetics, including myoelectrically controlled prostheses which use the clients’ neural network
• Spinal orthotic management, such as Scoliosis management and stabilisation of the spine post-fracture using invasive halo-traction techniques
• Plagiocephaly management, being the molding of an infant’s skull using a custom-made helmet to promote symmetry

Risk to the client group
Orthotist/Prosthetists provide services to vulnerable subsets of the Australian community, being the elderly, children and people with chronic conditions and permanent physical disabilities. Coupled with the physical presentation, Orthotist/Prosthetists may also be required to appropriately interact with clients affected by cognitive and communication impairments. Examples of the diversity of clinical services include:
• Aged care and the elderly; the provision of devices to promote mobility, independence and the maintenance of Activities of Daily Living (ADLs)
• Paediatrics; promoting mobility and independence for children with physical and developmental disabilities
• Chronic condition management; supporting and relieving discomfort from symptoms, or to control the progression of deformity
• Complex physical disability management; including people with a multitude of physical presentations, of varying complexity. This may include physical disabilities associated with trauma, neurological, degenerative and genetic conditions.

The populations receiving orthotic and prosthetic services are often from the most socio-economically challenged sectors of our community, and are therefore extremely vulnerable. These client groups require support and protection when accessing orthotic and prosthetic services.

A Chiropractor developed a back “brace” and billed Medicare, Medicaid, and private insurance companies over US $1000 each time he prescribed it, submitting it under the code for a “custom-fitted lumbral sacral orthosis”. Government and clinical experts testified that the “brace” did not fall within the category, was worth approximately $50 and should be deemed a “back belt”. The Chiropractor targeted persons who were elderly, low-income, or had disabilities to attend his “clinics,” where the preferred method of treatment was the back belt, with a total billing of $2 million in less than two years. A jury convicted the Chiropractor of health care fraud, fraudulent concealment of health care benefits, and money laundering.

Similar examples of this type of fraud exist within Australia, such as the well-known case of Professor Kossman at The Alfred Hospital. The Professor billed TAC duplications of the same intervention, being the application of Halo Traction devices. Not only was TAC billed sometimes up to 3 times for the same device for one patient, but these devices were actually applied by an Orthotist not Professor Kossman. The Professor’s billing procedures and practices have been extensively investigated and TAC proceeded with prosecution via the Victoria Police 10.

10 Medicare Fraud, USA, 28 February 2008
Consequences of poor practice

The potential consequence of poor orthotic and prosthetic practice is difficult to assess. The risk in the extreme case may be death or serious injury. Other consequences of inappropriate orthotic and prosthetic management may include the following:

- **Skin irritation and allergic reaction** associated with the improper handling of manufacturing chemicals and/or prescription of device materials, possibly leading to further medical intervention and period of non-use of a device
- **Falls**, possibly resulting in fractures or other injuries, leading to hospital admission, decreased client confidence and functional levels
- **Amputation**, including digits of the feet or lower limb, resulting in significantly compromised mobility and activity levels and an altered biomechanical structure
- **Ulceration**, leading to surgical debridement and minor wound management and resulting in lengthy hospital readmissions, reduced mobility and functional capacity
- **Muscular damage** such as contracture development, resulting in reduced rehabilitation and/or function
- **Unsuccessful post-rehabilitation period**, resulting in reduced functional level and community participation
- **Unsuccessful post-surgical period**, resulting in further surgical or rehabilitation intervention
- **Local and/or systemic infection**, leading to medical intervention and hospitalisation
- **Societal costs and the burden of disability** associated with an individual becoming non-ambulant. Reduced ambulatory levels affects employment, community participation and the need for carer support services.

Further to this, non-ambulant individuals may require major home modifications and wheelchair provision.

Areas of risk to the client group

There are key areas of risk in orthotic and prosthetic practice where the client is exposed to the potential for serious injury, as outlined below. A more specific and exhaustive list of risks and consequences are provided in Appendix One, see page 34.

- **Rehabilitation program design and implementation** – such as inappropriate rehabilitation discharge with a device for primary mobility, placing the client at risk of falls and subsequent injury.
- **Prescription and design of a device** – including inappropriate selection of materials and components, resulting in an inferior device, and a poor rehabilitation outcome.
- **Manufacture of a device** - including failure to observe technical recommendations and/or material specifications, resulting in an inferior device which is prone to failure and increases the risk of falls.
- **Fitting and supply of a device** – such as questionable competence in the assessment of the fit of a device, placing the client at risk of pressure areas.
- **Observation of regulations and protocol** - such as the failure to observe Therapeutic Goods Administration regulations regarding single use devices, placing the client at risk of infection or injury due device failure.
- **Client and team communication** – such as the poor explanation of don/doff procedures, increasing the risk of falls and pressure area development.

A total of 13 types of procedures undertaken by health practitioners have been identified as carrying risk. Some overseas jurisdictions have restricted these activities to
being carried out by registered practitioners only\textsuperscript{11}. The application of these risks to orthotic and prosthetic practice is outlined in Appendix Two, see page 39.

Potential for fatal and serious injuries

Whilst The AOPA Inc. has not received formal complaints against members involving fatal outcomes, an investigation into the death of a patient undergoing orthotic management has occurred and there have been a number of complaints relating to device failures and competence, with the potential for serious injury.

\textit{“Empirical information on the prevalence of death, injury, disability and mental distress caused by inadequate professional competence or malicious, discourteous or abusive conduct is not available. Even if it were, it would be difficult to cost. What price do we put on the benefits of patients’ peace of mind and public confidence?”}\textsuperscript{12}

In 2006, The Coroner’s Court of Tasmania investigated the death of an elderly gentleman, associated with the improper application of a halo brace, by an Orthopaedic Team and a Plaster Technician. This significant case highlights an area of high-risk practice, and the potential for fatal and serious injuries when services are provided by inappropriately trained or non-specialist professionals. Due to the importance of this case, the full details are outlined in Appendix Three, see page 40.

RehabTech at The Caulfield General Medical Centre conducted a nation-wide \textit{prosthesis} failure summary in 2005. This covered all reviewed failures over a 5 year period nationally. The summary reported 202 failures, involving 212 components. Lower limb prosthetic components were the main failures (89%), predominately attributed to design fault (21%) and mis-assembly (20%).

A 50 year old lady weighing 85 Kg was wearing a transfemoral prosthesis when the pylon catastrophically failed through snapping. The Prosthetist described her activity level as ‘low - medium’. The pylon fractured after only 8 months. On professional investigation it was found to have failed by fatigue. The pylon had been placed in a vise during assembly and should never have been fitted due to the scratches caused by the vise.\textsuperscript{13}

These figures highlight Prosthetist technical skill as a major factor in device failure, with client mis-use, device age and external damage collectively representing only 8%. The prosthetic socket failed in 3.8% of cases, compared to failures attributed to pylons (23.7%), feet (21.7%) and knee units (19.3%). Of concern is that only 6.9% of components were removed prior to failure.\textsuperscript{13}

Examples of component failures attributed to poor technical practice can be separated into two areas:

- Poor alignment of the prosthesis; where a component is set up at its extreme limits (Figure 1). On cyclic use the weakest aspect will fail (Figure 2).

\textbf{Figure 1:} An example of extreme alignment, resulting in areas of high stress.\textsuperscript{12}

\textbf{Figure 2:} Cracks within the tube clamp due to extreme alignment.\textsuperscript{13}

\textsuperscript{11} AMHAC, 2011, p.71-72
\textsuperscript{12} Secretary of State for Health, UK, 2007, p.20
\textsuperscript{13} RehabTech (Monash University), 2005
• Misassembly of the prosthesis: this can occur in numerous ways, with a primary error being the use of non-compatible components. For example, a pylon and clamp from different manufacturers may be reported as 30mm diameter. However they measure 29.94mm and 30.04mm and are not compatible.

There are few incidents on public record of client injury which have proceeded to litigation, as cases are predominantly settled out of court. It can be assumed that the prevalence of device failure or practitioner malpractice is far higher than that indicated by formal complaints and litigation.

**Cameron v Otto Bock Inc [1994]**

In 1991, Mr. Cameron, a trans-tibial amputee since 1965, fell when the Otto Bock Orthopedic Industry, Inc. ("Otto Bock") pylon in his prosthesis broke. Mr. Cameron suffered a fractured pelvis and emotional damage from the fall, therefore suing Otto Bock in federal court, charging negligence and breach of warranty. Each side attributed the failure to a different cause. The patient claimed the pylon and clamp had been negligently and defectively designed. Otto Bock's expert testified that the prosthesis broke because the screw that fastened the pylon to the clamp had been screwed too tightly by the Prosthetist, despite a warning against overtightening by Otto Bock. The jury found in favor of Otto Bock.

Between July 2005 and July 2010 The AOPA Inc. received 8 complaints from the public, other health professionals and third party funders regarding Australian Orthotist/Prosthetists. Of the 8 complaints, 4 were serious claims of malpractice and questioned clinical competency. Other complaints were regarding unprofessional conduct, inappropriate client management and fraudulent representation. As a non-regulated profession, The Association is often restricted in its ability to action complaints, especially regarding those of non-members.

**The AOPA Inc. Complaints:**

**July 2007**

An elderly client was referred for a knee orthosis to relieve severe knee pain. Over a two year period she attended 9 appointments, was measured on 3 occasions and was regularly advised that the orthosis was on order. She was originally informed that there would be no cost involved as she was on a full pension. After 2 years however she was requested to pay $900 for an off-the-shelf device or $1800 for a custom made device, and the device would be ordered/manufactured upon payment.

**February 2008**

A client with a complex presentation, requiring upper limb orthoses complained regarding the professionalism and competence of her treating Orthotist. The orthoses provided were ill-fitting and did not achieve their intended goals. The orthoses caused numerous pressure sores which required ongoing treatment and an extended period of not being able to wear orthoses.

Professional regulation legislation has been passed in the United Kingdom, which included Orthotist/Prosthetists. Currently there are 865 registered Orthotist/Prosthetists in the UK (January 2010). In 2009-10 the regulatory body, The Health Professions Council UK, reported a 37% increase in complaints against members compared to 2008-09, with 7 cases against Orthotists/Prosthetists. The increase in complaints is possibly due to increased use of the complaints process, which suggests that Australian complaint numbers may increase if regulation and a robust complaint process were implemented.
Risk to the wider public

Due to the vulnerability of the client groups requiring orthotic and prosthetic services, the impact of inadequate clinical competence and unprofessional conduct extends far beyond the client involved. Many orthotic and prosthetic device users are reliant on their equipment to complete ADLs, participate in family activities, maintain employment, and continue a full and active social life. Community participation and employment is not only essential for individual growth and a healthy psychosocial status, but also for the growth of the community as a whole.

Risk to the Orthotist/Prosthetist

“While the orthotics and prosthetics field is rapidly adding evidence-based knowledge, proven best practices, and post-graduate professionals, it is also fabricating its numerous products and devices in different ways and with different materials than it did in the past. New methods and materials most often result in superior techniques and devices, but they also bring with them new environmental and safety hazards”14.

Due to the nature of orthotic and prosthetic devices, a degree of risk exists in the manufacturing process. A qualified Orthotist/Prosthetist is trained extensively in materials technology and occupational health and safety, and is aware of the hazards to themselves, their colleagues and their clients, and how best to minimise these. Professional regulation has the potential to improve workplace safety through the removal of unqualified individuals who employ unsafe manufacturing techniques and may establish private practices which may elude the safety net of the Occupational Health and Safety legislation.

Exposure to risk

“In the prosthetic fabrication process, a number of occupational hazards exist. These include chemical contaminants, airborne contaminants, and noise pollution”15.

Orthotist/Prosthetists are exposed to environmental and safety hazards in 3 key stages of practice:

Phase One: Nuisance dust from plaster casting and modification

The process of taking a negative cast and creating a positive model creates nuisance dust. A build up of dust in the lungs can have an adverse effect, depending on the individual’s immune system response. The risk from nuisance dusts depends on the specific practices of the facility. Fillers, which are used to make positive models lighter, such as large spinal brace casts, contain crystalline quartz silica, which is a human carcinogen16.

Phase Two: Chemical fumes from fabrication

The fabrication process exposes practitioners to the risk of burns from ovens which heat plastic to 220°C. Further to this, the heating of these materials also creates volatile emissions. The Orthotist/Prosthetist is also exposed to styrene monomers and vinyl ester resin, both of which are known carcinogens16 during the attachment of prosthetic components to the diagnostic socket (known as "gunking"). Exposure to fumes and chemicals also occurs during the lamination process.

Phase Three: Noise hazards from fitting

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14 Keeter, 2009, p.1
15 McCay, 2001, p.1
16 Keeter, 2009
Preparing a device for fitting to a client involves grinding which produces more nuisance dust and noise hazard. A normal conversation is held at 60 decibels (dBA), with shouting registering 110 dBA. Hearing damage can occur when an individual is exposed to noise levels of 85 dBA for 8 hours. Orthotist/Prosthetists are consistently exposed to noise above 85 dBA (a pneumatic drill is 120 dBA) and therefore the possibility of hearing loss is likely. In a study of occupational hazards in the prosthetic workplace\textsuperscript{17}, 12.4\% of respondents suffered hearing loss.

**Nature and severity of the risk**

The prosthetic workplace study involved 97 United States facilities. Almost all of the products studied within these facilities were found to be an irritant to the eyes, skin, and respiratory system\textsuperscript{17}. Of special concern was:

- Unsaturated polyester resin: can cause lung injury; possible carcinogen; causes birth defects in laboratory animals; can affect the auditory system
- Epoxy Vinyl Ester Resin: possible carcinogen; can affect the auditory system
- Hardener for Pedilan Foam: can cause corneal damage
- Naugatuck Promoter: can cause irreversible eye damage
- Rubber Cement: has caused birth defects in laboratory animals\textsuperscript{17}.

Most concerning is the presence of **styrene, acetone and toluene** in the products used for manufacture, as well as carbon fibres and the associated dust\textsuperscript{17}.

**Styrene** is an ingredient in many laminating resins. Approximately 35\% of technicians use polyester resin 1-3 times per week or more. The inhalation of high levels of styrene can result in nervous system effects such as depression, concentration problems, muscle weakness, tiredness, and nausea. It is also known to cause eye, nose and throat irritation and possibly cancer in humans\textsuperscript{18}.

**Acetone** is used daily by 75\% of Orthotist/Prosthetists. Inhalation of moderate to high levels for short periods can cause nose, throat, lung, and eye irritation, headaches, light headedness, confusion, increased pulse rate, effects on blood, nausea, vomiting, unconsciousness and possible coma\textsuperscript{19}. Exposure during pregnancy is associated with risk of malformations and miscarriages\textsuperscript{19}.

**Toluene** is found in contact cements or glues. It is used daily by 85\% of Orthotist/Prosthetists. Low to moderate levels from long-term exposure can cause tiredness, confusion, weakness, drunken type actions, memory loss, nausea and loss of appetite, and hearing loss. It can also cause memory loss and decreased mental ability. Exposure during pregnancy can cause growth and developmental deformities\textsuperscript{18}.

**Carbon fibre and carbon fibre dust** can cause skin and respiratory irritation, contact dermatitis and possibly chronic interstitial lung disease. The particle sizes in common use are unlikely to be respirable. However, carbon dust from machining may be very fine and should be considered respirable\textsuperscript{18}.

**Risk to the environment**

The risk to the environment from the orthotic and prosthetic profession may not be obvious however consideration should be given to the disposal of manufacturing materials and obsolete devices.

\textsuperscript{17} McCay, 2001

\textsuperscript{18} McCay, 2001

\textsuperscript{19} Sohail, et al, 2000
"The demands on the prosthetics industry are several fold - comfort for the patient, biocompatibility, high performance and versatility to enable patients to lead as normal a life as possible. And even in an industry that focuses heavily on the patient, green technologies and carbon emissions need to be considered".

Aside from the health risks associated with the current manufacturing processes, waste off cuts and obsolete devices are not biodegradable. In an attempt to produce “greener” prostheses, a prosthetic socket has been made entirely from composite plant materials however this technology is far from entering the current market.

Materials such as acetone and carbon fibre are hazardous to the environment and the disposal of these materials should follow protocol. The environment and public should not be unduly exposed to these chemicals due to improper disposal. Orthotist/Prosthetists must consider the environmental impact when selecting manufacturing materials and the method of waste disposal.

Future risks

The changing health needs of Australia further increase the demand for orthotic and prosthetic services. With this increase in demand is an evolving clinical setting including community based care and hospital in the home, which places increased time pressure on clinicians.

The United States has seen an unprecedented increase in orthotic sales due to a rise in geriatric population numbers and the changing service model. This increases the potential for service provision by untrained professionals and the likelihood of other allied health professionals providing ‘quick fit’ pre-fabricated orthoses. The provision of pre-fabricated orthoses without customisation by an Orthotist/Prosthetist may be considered a ‘placebo’ device in which the client is not provided with the most appropriate device for their circumstances. This practice has the potential to compromise client function and safety.

In the last decade there have been numerous developments in orthotic and prosthetic technology and clinical practice. The advancements highlight increasingly invasive and high risk practices, such as; osseointegration, Functional Electrical Stimulation, implantable myosites, piezoelectric power generation, electronically controlled orthoses, walking machines, microprocessor controlled prostheses, nanotube laminations and mini-driver systems.

Further to technological advancements and the pressure from an aging population, extended scope of practice is increasing the expectations on Orthotist/Prosthetists.

20 Brown, 2010. p.1
21 University of Strathclyde, 2009
22 Stark, 2010
23 Turnbull, et al., 2009
In some areas Orthotist/Prosthetists are required to perform diagnostic testing, provide referrals and develop prescriptions in isolation of a multidisciplinary team.

Extended scope of practice exists across the entire orthotics and prosthetics profession. Examples include the development of client prescriptions without multidisciplinary consultation, or the managing of large budgets and equipment schemes in major hospitals, therefore having discretionary power regarding client access and equity. The Orthotist/Prosthetist is an allied health practitioner with diverse training and skill, and therefore is readily adaptable to providing extended scope of practice services. Whilst the profession is unregulated however, this practice presents a risk for the client and employer, with minimal controls in place to monitor the qualifications and competency of those granted increased responsibilities.

Conclusion

The compounding changes within the health system, coupled with technological advancements, increase the risk to public safety. The orthotic and prosthetic client is exposed to a variety of risks, such as the competence and skill of their practitioner and the impact of materials, technology and design. The Orthotist/Prosthetist is also exposed to the hazards associated with device manufacture. The industry is advancing at a rapid rate due to the incorporation of digital and mechanical advancements. The accumulation of these factors further highlights the need for a regulated profession to protect the interests and safety of the public.
4.3 Criterion Three

Failure of Other Regulatory Mechanisms

Currently, there are no registration requirements for Orthotist/Prosthetists in Australia. Government regulations, international standards and professional membership exist, however these mechanisms are not far-reaching enough or mandatory. Therefore the necessary quality assurance standards for the professional practice of Orthotist/Prosthetists are not in place, and the removal of public risk is not assured.

Short-comings of existing mechanisms

National regulations and legislations, such as the Occupational Health and Safety and the Therapeutic Goods Act (TGA) monitor the risks associated with clinical practice techniques and hazardous materials. These regulatory mechanisms fail to monitor practice and ensure safe clinical services for orthotic and prosthetic clients nationally.

Australian Orthotist/Prosthetists are subject to statutory laws against criminal behaviour. The public is also able to proceed with civil claims and criminal prosecution in relation to grossly unethical and incompetent conduct.

In 2003 a male Orthotist, based in London, was convicted of sexual assault of a female patient under 16 years of age. This conviction was found to impair his fitness to practice and he had brought the profession into disrepute. His actions were found to have breached the trust which is required by the public in a health professional and the Registrar was directed to strike him from the register, rendering him unable to practice in the United Kingdom.

Mechanisms such as The Fair Trading and Trade Practices Act and the Health Care Complaints Commission are available to investigate complaints into false, misleading or deceptive conduct and issues surrounding the provision of health services. These processes are extensive and exhaustive and current use suggests the public may not see these mechanisms as appropriate avenues. The law does not stipulate a minimum level of qualification or standard of professional conduct, and intervenes only against criminal behaviour.

The provision of orthotic and prosthetic services in Australia is subject to meeting the Medical Devices Regulation (MDR) of the TGA. Orthotist/Prosthetists are considered to be manufacturers of medical devices and must meet the requirements of the manufacturer as set by the TGA. At the core of the MDR is the requirement that “a medical device be designed and produced in a way that ensures that the device will not compromise the clinical condition and safety of a patient ... and that any risks associated with the use of the device are acceptable when weighed against the benefit to the patient.”

The assessment of facility and individual practitioner conformity to the TGA is based on a principle of risk. This means that high risk practices will be more closely monitored. Small, private based orthotic and prosthetic practitioners represent a low risk and are unlikely to receive scrutiny. Therefore the Act falls well short of short of monitoring the quality and safety of orthotic and prosthetic services in Australia.

24 Anderson & Tiernan, 2009, p.1
Limitations of self-regulation

Membership to The AOPA Inc. requires a minimum qualification of “Bachelor of Prosthetics and Orthotics from La Trobe University or an equivalent tertiary Prosthetic and Orthotic qualification as determined by the AOPA Inc. Certification Committee”. In addition to a minimum tertiary qualification The AOPA Inc. requires its members adhere to defined standards and by-laws, outlined in the following documents:

- Competency Standards (2003)
- Ethical Code and Professional Conduct (2010)
- Mandatory Continuous Professional Development (2010)

Members who fail to adhere to these standards can be found in breach of membership criteria, and suspended or removed from The Association. However The AOPA Inc. remains powerless to prevent omitted individuals from practicing.

“In Australia today, the national workforce grows at an annual rate of around 170,000 per year. By 2020 this is predicted to be just 12,500 per year; . . . unless this outlook changes the next twenty to thirty years will see an increasing, and unprecedented, focus on obtaining (and keeping) the Australian workforce, including the health workforce”26.

Issues with equivalency of international qualifications

Within the public health sector nationally, Orthotist/Prosthetists are classified in the Professional Stream, requiring a Degree in Prosthetics and Orthotics. This baseline for employment fails to assess the equivalency of applicants and employees with international qualifications. There are numerous International Bachelor Degrees that are not equivalent to the La Trobe qualification. The criterion for public sector employment fails to distinguish this difference.

There are no minimum qualification requirements in the private sector. A recent Association workforce survey indicates that the private sector employs 53% of Australian Orthotist/Prosthetists. Therefore, 47% of Orthotist/Prosthetist positions are semi-regulated regarding qualifications and the other 53% have no qualification controls in place at all.

Safely addressing the Orthotist/Prosthetist workforce shortage

Australia has an estimated Orthotist/Prosthetist workforce of 344, of which 258 are members of The AOPA Inc. This represents a low ratio per capita of only one professional per 65,341 population. The British Association of Prosthetists Orthotists (BAPO) suggests a ratio of one Orthotist per 30,555 population27. Based on this internationally accepted benchmark approximately 736 Orthotists would be required to meet current population demands. According to The Association’s workforce survey, individuals practicing solely as Orthotists represent 65% of the Australian workforce.

26 Australian Health Minister’s Conference, 2004, p.9
27 NHS Scotland, 2005
Orthotist/Prosthetist workforce. Therefore, a workforce of 1132 would be required to meet the entire orthotic and prosthetic needs of the Australian population.

Internationally qualified professionals offer an opportunity to address the skill shortage within Australia. With this however is an unmanaged risk to public safety and welfare whilst the “equivalency” of these individuals’ qualifications is unable to be assessed. The Association is currently in negotiations with La Trobe University regarding the development of a competency exam. This will assist with addressing equivalency issues of international applicants however, without regulation this procedure is unable to restrict the practice of non-equivalent individuals.

The AOPA Inc. fields numerous international membership enquiries on a monthly basis, with many from individuals without formal qualifications. From 2007 to 2009 a total of 13 applications were received, with 9 during 2009. These individuals are able to practice in an unmonitored and unregulated manner, regardless of The AOPA Inc.’s decision on membership eligibility. Regulation of the profession has the potential to increase the portability of international practitioners, through a streamlined and transparent process of qualification recognition.

With reduced workforce numbers and increasing selectivity about where practitioners work, it is possible that only employers and locations of choice will have ‘adequate’ staffing. Increasing pressure will be placed on ‘non-choice’ employers to accept non-member applicants, with a subsequent decrease in the service quality and increased client safety risk.

The AOPA Inc. acknowledges the recruitment and retention issues, especially in rural and remote areas. The employment of unqualified professionals is a risk to client safety and is not an appropriate solution to workforce recruitment and retention issues. This practice will increase without national professional regulation.

**Powerless to restrict orthotic and prosthetic practice**

As of July 2011, there are 8 applicants who do not clearly meet The AOPA Inc. eligibility criteria. A competency exam is the only means for assessing the equivalency of these individuals’ education. As Orthotist/Prosthetists are currently unregulated these applicants are free to practice. Currently, 4 applicants with international qualifications are practicing within Australia public and private facilities.

There are no restrictions on the provision of private clinical services, irrespective of qualifications. Non-qualified individuals are able to use the title of Orthotist/Prosthetist and/or practice in this area. Further to providing a safe haven for individuals unable to practice internationally, it also allows individuals with low level qualifications, such as overseas certificates in orthotic and prosthetic technology or technical based training, to offer clinical services to the Australian public. Due to the lack of title restrictions it is the publics’ responsibility to distinguish the difference between an appropriately qualified professional and an individual claiming skill and expertise.

**Promoting public safety within current limitations**

The AOPA Inc. endeavors to promote public safety within the limitations of a voluntary association through numerous processes including the “Search for an Orthotist/Prosthetist” function on The AOPA Inc. website. This allows the public, funding agencies and potential

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28 Australian Health Minister’s Conference, 2004
employers to check the currency of a practitioner’s membership. The Association also provides Private Health Insurance companies and other funders with notification of Association membership status for Orthotist/Prosthetists on request.

A Complaints and Grievances Procedure provides the public and health professionals with an avenue for registering formal complaints regarding unprofessional conduct, financial exploitation, fraudulent representation and competency and negligence issues. The Association is restricted in the actions it may take, being powerless to act against non-member Orthotist/Prosthetists and unable to prevent expelled members from practicing. “Within such an unregulated service delivery environment, professional associations have developed as de facto registration boards, monitoring complaints from the public and providing continuing education to assist in maintaining and improving the quality of service delivery. Membership of such professional associations is not enforceable however . . .”29.

Between July 2005 and July 2010 The AOPA Inc. received 8 complaints from the public, other health professionals and third party funders regarding Australian Orthotist/Prosthetists. Two complaints were regarding non-members and 3 regarding longstanding members who elected to cancel their membership during the investigation process. These members had a mean of 9.66 membership years, suggesting the cessation of membership in order to avoid the Complaints and Grievance procedure. The Association was left powerless to act, and unable to offer public protection.

Conclusion

The existing regulatory processes are disjointed mechanisms, without the common purpose of public protection. These mechanisms are not far-reaching enough and fail to prevent clinical practice by unqualified individuals or impact at the client-level. Currently it is the client’s responsibility to ensure they receive services from an appropriately qualified and competent practitioner. In light of the vulnerability of the orthotic and prosthetic client group, employers, The AOPA Inc. and the Australian Government have a duty to ensure public safety and promote the provision of high quality orthotic and prosthetic services by appropriately qualified and regulated health care professionals.

29 Turnbull, et.al, 2009
4.4 Criterion Four

Possibility of implementing regulation

The contemporary role of the Orthotist/Prosthetist is well-defined, with an established body of teachable knowledge, internationally accepted standards of practice and functional competencies. The orthotic and prosthetic profession is well placed to operate alongside its allied counterparts in the new regulatory framework.

Contemporary role of the Orthotist/Prosthetist

Orthotist/Prosthetists are university trained allied health professionals responsible for the clinical assessment, prescription/design, manufacture and fitting of prostheses and orthoses. The orthotic and prosthetic practitioner requires "the theoretical knowledge of anatomy, physiology, biomechanics, and prosthetic and orthotic prescription, design and fabrication, enhanced by strong practical skills in research methodology, clinical assessment, and the application of prosthetic and orthotic techniques"30.

Many Orthotist/Prosthetists specialise due to the complex nature of the orthotic and prosthetic client group. Specialty areas may include; spinal, paediatrics, diabetes, rheumatology, stroke, head injuries, lower limb, upper limb and foot and ankle complex. "A specialist Orthotist/Prosthetist will have developed skills by evidence based and reflective clinical practice, and peer group appraisal. They will have demonstrated an increased depth of understanding within the specialty which has increased their clinical reasoning and decision making ability"31.

Body of knowledge of the profession

The orthotic and prosthetic profession has advanced to a highly professional and integrated part of the healthcare system. The Australian-based training program has progressed from a Diploma, to a Degree, and more recently a minimum education level of Masters has been established with the first student intake in 2009.

The orthotic and prosthetic body of knowledge is gained from numerous disciplines to create a health care practitioner with a broad understanding of health, physics and materials technology. Major areas of undergraduate study include prosthetics, orthotics, anatomy, physiology, materials and biomechanics. These draw from the disciplines of human biosciences, biomedical sciences, social sciences and health sciences. La Trobe University also supports a PhD program which promotes Australian-based research and the development of a nationally relevant knowledge base.

Internationally a number of organisations produce evidence-based materials for the advancement of the Orthotist/Prosthetist knowledge-base and promotion of best practice. The International Society for Prosthetics and Orthotics (ISPO) has produced numerous reports from Consensus Conferences in areas such as Cerebral Palsy management, the Orthotic Management of Stroke Patients and Lower Limb Prosthetic components.

The American Academy of Orthotists Prosthetists (AAOP) receives funding from the U.S. Department of Education in order “to move the profession toward evidence-based practice by expanding the O&P knowledge base, offering

30 La Trobe University, 2010

31 AAOP, 2010
clinical guidance, defining best practices and identifying research priorities”. The AAOP has published an extensive range of Official Findings of State-of-the-Science Conferences, examples include upper and lower limb prosthetic outcome measures, the biomechanics of partial foot amputation, knee-ankle-foot orthoses for ambulation, orthotic management of the neuropathic foot and the orthotic management of deformational Plagiocephaly, Brachycephaly and Scaphocephaly.

Functional competencies of the profession

The functional competencies of the Australian Orthotist/Prosthetist are clearly established through the following Association documents:

- The AOPA Inc. competency standards (2003)
- The AOPA Inc. minimum standards for membership (Statement of Rules and Purposes, 2008)
- Position papers on specific areas, such as Therapeutic Goods Act (2006) and Device Modification (2009)

Supporting the ongoing clinical development of Orthotist/Prosthetists, The Association has implemented a Mandatory Continuing Professional Development Program. This ensures practitioner’s knowledge base remains up-to-date and the competencies and expectations of the profession are understood.

Categorisation and training of Orthotist/Prosthetists

The accreditation of orthotic and prosthetic training facilities is a complex international process. The ISPO and WHO have outlined the professional profile of an Orthotist/Prosthetist and a framework for the training of Category I practitioners.

“Category I personnel are educated and trained in all areas of prosthetics and orthotics practice and related rehabilitation issues whilst Category II personnel are educated and trained in only the major areas of prosthetics and orthotics which are commonly needed”\(^{32}\).

The Master of Prosthetics and Orthotics at La Trobe University is the only training program for Orthotist/Prosthetists in Australia. Until 2009 this program was a Degree, and this established the minimum educational requirement for entry into The AOPA Inc. The educational program at La Trobe University has been certified according to the WHO/ISPO classification system as Category I and is thus accredited internationally.

This categorisation does not address the issue of classification of international qualifications in Australia. All Category I courses do not produce Orthotist/Prosthetists of “equivalent” clinical and technical skill and standard to the La Trobe University Bachelor Degree. The WHO/ISPO guideline for categorisation and training of practitioners focuses on meeting the large need in developing countries.

The ISPO categorisation process does not simply assess the education program, but also its ability to progress the profession within country. For example, the Orthotist/Prosthetists trained in the Category I program in Tanzania do not have the same educational standard as a graduate from La Trobe University Australia, but they meet the highest level of orthotic and prosthetic education required to perform the role of an Orthotist/Prosthetist in their country.

\(^{32}\) WHO, 2005, p.10
Conclusion

The orthotic and prosthetic profession is well-defined, with a clear evidence-based body of knowledge and defined competency standards. The minimum standard of orthotic and prosthetic education in Australia is provided by an internationally accredited program. Internationally trained Orthotist/Prosthetists present a challenge to the Australian Orthotic and Prosthetic Association in order to determine “equivalency”. On the other hand, our Australian-trained practitioners are eligible for membership into any association and regulatory body in the world, due to the high educational standard of the Australian program.

4.5 Criterion Five

The practicality of implementing regulation

The leadership of the Australian orthotic and prosthetic profession includes The AOPA Inc. National Council (representing The Association), and representatives of the NCPO and ISPO Australian National Member Society. In seeking inclusion in the single NRAS, this leadership group is committed to serving the interests of the public over occupational self-interests.

Self-regulation remains impractical

The AOPA Inc. is the peak professional body for Orthotist/Prosthetists in Australia and supports the safety and welfare of the public, through its objective to “promote honourable practice, eliminate malpractice and decide questions of professional usage and courtesy among Orthotists and Prosthetists”.

As membership of The AOPA Inc. is voluntary, The Association is limited in its ability to protect and serve the public, as its standards do not reach all practicing Orthotist/Prosthetists. A number of workplaces demonstrate a commitment to public safety by employing AOPA Inc. members only however, many employers simply request AOPA Inc eligibility. Therefore, self-regulation of the profession remains impractical whilst The Association has no regulatory power.

To date, there are 258 AOPA members practicing in Australia with a recent workforce survey indicating that 75% of practicing Orthotist/Prosthetists are members of the peak professional body. This suggests that approximately 86 Orthotist/Prosthetists may be practicing outside any professional Codes of Practice and Competency Standards. Although this number is low, there is no ability to collect data on the number of non-trained individuals practicing privately, or other professionals providing services, due to the lack of title restrictions and an enforceable Scope of Practice. Further to this, without regulation it is not possible to accurately canvas the workforce. This restricts the collection of data regarding education and training needs, client numbers and client service requirements.

Commitment of the profession and its’ leaders to regulation

The commitment of the orthotic and prosthetic profession and its leaders to national regulation is evident through the actions of The AOPA Inc. and the support provided by the membership base. Continued membership growth over the last 5 years reflects satisfaction with the improved governance and strategic focus. Public interest and safety is at the forefront of The Association’s objectives.
Serving the public interest

The Association demonstrates its commitment to maintaining and promoting a safe and sustainable workforce through the following standards and procedures:

- Competency Standards (2003)
- minimum standards for membership (Statement of Rules and Purposes, 2008)
- Ethical Code and Professional Conduct By-law (2010)
- Mandatory Continuing Professional Development Program By-law (2010)

Organisation and commitment of the membership

Mandatory CPD was proposed at the 2008 Annual General Meeting and supported by the membership unopposed. This program was rolled out in July 2009, with 2010 membership renewals dependent on meeting CPD requirements. The membership has shown strong support of the process, with only 3 failing to meet requirements for the 2009/10 financial year.

The Dispute and Grievance Procedure has also been strengthened in recent years. This provides a platform for the public, health professionals and Orthotist/Prosthetists to lodge complaints regarding Australian Orthotist/Prosthetists, within the limitations of a non-mandatory association.

The Association is committed to increasing the population of Orthotist/Prosthetists in Australia to address the unmet need and skills shortage. The AOPA Inc. continues to liaise with La Trobe University regarding a competency based assessment for international qualified practitioners. This aims to evaluate competency and allow appropriately trained international professionals to gain employment within Australia, whilst maintaining national standards of clinical and technical excellence. This process demonstrates a commitment to the public interest and safety.

Addressing the financial implications of regulation

The AOPA Inc. is currently a self-funded association with small member numbers. There is currently a skills shortage, with the number of practitioners required to meet the current demands projected as 1132. Therefore, with the aging population and increasing chronic conditions, the orthotic and prosthetic workforce will grow in line with other allied health professions over the next decade.

Currently a number of allied health professions are regulated in Queensland. The Dental Technicians profession is regulated with 966 members. The Office of Health Practitioner Registration Boards reports that the Boards of Queensland are fully funded from registrants fees. The AHMAC reports annual registration fees for the currently regulated professions range from $115 to $650, with an unweighted average of $385 per year

Therefore, The Association does not view small professional numbers as a barrier to achieving financial stability in regulation, and increasing public protection.

Conclusion

Key areas of recent profession development, such as Mandatory CPD and the Grievance and Dispute procedure are designed by the leaders of the profession, and ratified by the Australian membership. This highlights a commitment from the occupational leaders to favour the public interest over occupation self-interest, which is well supported by the members of the profession.

33 AHMAC, 2011, p.27
4.6 Criterion Six

The benefits to the public of regulation

“First, the overriding interest of professional regulation must be the safety and quality of the care that patients receive from health professionals . . . professional regulation should not create unnecessary burdens, but proportionate to the risk it addresses - the benefit it brings”34.

Inclusion of the orthotic and prosthetic profession in the NRAS will provide a solid basis for monitoring the risks to public safety that may arise from unregulated Orthotist/Prosthetists working outside of a quality framework. Key design features of the Scheme minimise the potential negative impacts that have impeded national registration in the past.

The rationale of occupational regulation is to protect the interest of the public and promote health and safety by guaranteeing a mandatory quality standard. Positives extend beyond the immediate protection of the public, to promoting a mobile orthotic and prosthetic workforce and appropriately managing skill shortages and the associated risks, which ultimately benefits the public.

A primary concern with the regulation of Orthotist/Prosthetists is the exacerbation of the current skills shortage. Employers with re-occurring recruitment issues, often resorting to employing unqualified Orthotist/Prosthetists, may face increased staffing difficulties. The AOPA Inc. does not consider a reduction in the qualifications and competency of health

34 Department of Health UK, 2007, p.6
professionals to be an adequate solution to workforce issues.

Examples of successful solutions to Orthotist/Prosthetist recruitment exist, such as the "Area of Needs" Scholarships in Brisbane. Successful candidates are provided with financial support during their final year of study and upon graduation, are indentured to a Queensland Health orthotic and prosthetic facility for twelve months. Queensland health is currently in the third cycle of new graduates under this scheme. The Queensland AOPA Inc. Representative reports success in recruiting and retaining clinicians and increasing the capability and capacity of the profession in Queensland.

The IGA has been designed with the potential positives and negatives of regulation in mind, and maintains a focus on:

- **The quality of health care services** – this focus is maintained through the 6 benchmarking criterion for inclusion. These criteria establish a minimum mandatory standard and focus on the public interest. The development of a profession specific board, including community members, one-third non-profession members and profession representatives, ensures the process is transparent. This transparency promotes quality health services and protects against profession self-interest, which does not exist in a self-regulatory environment.

- **The supply and availability of health professionals’ services** – by focusing the criteria on benchmarks related to health workforce mobility, flexibility, and access of supply.

- **The cost of health professionals services** – through the removal of barriers for workforce flexibility, addressing supply issues and focusing on sustainability. Improving the quality of health care services removes the costs associated with incompetence, malpractice and reduced consumer confidence.

Whilst focusing on these three areas, the IGA ensures multiple benefits to the public of regulating the orthotic and prosthetic profession, which significantly outweighs the negatives. They include;

- **Delivering a consistent approach to issues such as reservation of title, which is an important signifier of qualifications, expertise, experience, character, and fitness to practice.** The reservation of the title of Orthotist/Prosthetist will provide public confidence and protection through the guaranteeing of standards of practice, qualifications and competence. The restriction of title will assist the public to identify individuals practicing outside of the regulatory framework, with the complaints process providing an avenue for addressing concerns.

- **Providing the public with increased clarity regarding the pathways for lodging a complaint.** The public will have a clear and transparent pathway for lodging complaints, without concern regarding the objectivity of the process. The profession-specific board will ensure complaint management is transparent and without the short-comings of the self-regulated process that is currently in place. Further to this, restriction of title will ensure that no individual providing orthotic and prosthetic services is able to escape the safety net of regulation and the complaints procedure, regardless of qualification or professional membership status.

- **Locking in national standards to deliver quality, timely, flexible health care services to the public.** Regulation of Orthotist/Prosthetists will promote...
public confidence in individual practitioner’s qualifications and skills. Through the protection of title, regulation of the profession will also decrease the potential for false claims regarding qualifications and certification status. Australian employers will welcome the regulatory process, which will provide a clear recruitment guideline. A minimum qualification and competence standard will promote quality, timely and flexible health services, with improvements in the equity of service across Australia.

- **Overcoming the disadvantages associated with mutual recognition** as it presently operates and remove impediments to more efficient workforce deployment. Currently there are some variations between the states in the qualifications required for Orthotist/Prosthetist employment in the public sector. A national approach to regulation of the profession will provide greater clarity to employers and ensure that the standards of practice are consistent regardless of the service location.

- **Assisting with the collation of national statistics/data.** This provides opportunities for meaningful benchmarking of service provision nationally. Further to standardising service provision, regulation will enable the collection of national statistics on client services. This will promote a flexible and dynamic health service and ensuring the appropriateness of undergraduate and continuing professional education to meet the needs of the Australian community.

- **Facilitating a national, across-profession approach to the Orthotist/Prosthetist workforce.** A national workforce approach refers to the inclusion of the entire profession and using the subsequent data from these active professionals to develop strategic actions to address workforce issues. Currently the approach to Orthotist/Prosthetist workforce issues is fragmented. Through the linking of the national orthotic and prosthetic community, a greater understanding of client needs and practitioner educational requirements will be developed. Further to this, it will ensure an appropriate and standardised assessment of internationally recognised qualifications, and support the National Centre for Prosthetics and Orthotics in its delivery of quality education to meet the workforce needs of Australia.

**Conclusion**

A single national regulation scheme is the most appropriate method for regulating the orthotic and prosthetic profession. It will provide benefits to the public whilst minimising the potential negative impacts of other regulation models. These benefits to the public clearly outweigh any potential negative impact of regulation to the public, the national profession and the health-care system.
5. CONCLUSION

Technological developments and clinical changes in the last decade have seen increased ‘risk’ for clients requiring orthoses and prostheses. The fast pace of technological advancement, moving into high risk areas, such as neurological stimulation, is coupled with workforce sustainability issues and the changing framework for the provision of health. These issues provide an environment of risk for an already disadvantaged sector of the community when accessing disability services.

Orthotist/Prosthetists work across diverse areas of practice, managing a multitude client of presentations. The complex needs of the orthotic and prosthetic client demands a qualified and competent practitioner. The risk associated with orthotic and prosthetic practice is highlighted through a number of cases, mainly the recent patient death associated with the application of a halo-thoracic brace. The public should not bear the responsibility for identifying appropriately qualified individuals. A broad reaching regulatory system for allied health provides public assurance that entire treatment teams have met the standards set by regulation, with the reservation of title being an important signifier of a practitioner’s qualifications, expertise, experience and fitness to practice.

There have been extensive efforts by the orthotic and prosthetic profession to promote public well-being and safety. Many of these measures have fallen short due to the limitations of a voluntary organisation. This does however signify that the membership and leadership of the orthotic and prosthetic community are ready for change, and are committed to practicing within the regulatory framework.
## 6. APPENDIX ONE

Risks of practice and associated consequences

### Table 1: Risks to clients when Orthotist/Prosthetists provide an inadequate clinical service

<table>
<thead>
<tr>
<th>Risk</th>
<th>Potential Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate program design</td>
<td>Client does not achieve personal and mobility goals</td>
</tr>
<tr>
<td></td>
<td>Further interventions, such as surgical and pharmacological</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Inappropriate discharge from rehabilitation with a prosthetic or orthotic device required for primary mobility</td>
<td>Client unable to adequately function at home, therefore increasing the need for carers and/or admission to care facility</td>
</tr>
<tr>
<td></td>
<td>Re-hospitalisation for further rehabilitation</td>
</tr>
<tr>
<td></td>
<td>Home and/or community based falls</td>
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<tr>
<td></td>
<td>Reduced client confidence associated with falls</td>
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<tr>
<td></td>
<td>Fractures and subsequent hospitalisation due to falls</td>
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<tr>
<td></td>
<td>Development of muscular damage, such as contractures</td>
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<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Irregular client reviews to ensure components and materials are mechanically and technically sound</td>
<td>Failure of device resulting in inability to wear the device, impacting on functional, social and employment aspects of life</td>
</tr>
<tr>
<td></td>
<td>Superficial injury due to material failure, increasing risk of infection, skin breakdown etc</td>
</tr>
<tr>
<td></td>
<td>Failure of component/materials resulting in falls</td>
</tr>
<tr>
<td></td>
<td>Reduced client confidence associated with falls</td>
</tr>
<tr>
<td></td>
<td>Fractures and subsequent hospitalisation due to falls</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Irregular client reviews to ensure the device fit has been maintained</td>
<td>Superficial injury due to poor fit, increasing risk of infection and skin breakdown.</td>
</tr>
<tr>
<td></td>
<td>Development of muscular damage, such as contractures</td>
</tr>
<tr>
<td></td>
<td>Hospitalisation associated with superficial injury</td>
</tr>
<tr>
<td></td>
<td>Further medical intervention required, such as revision amputation surgery, debridements etc</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Poor client assessment and referral to allied health and medical specialists</td>
<td>Inappropriate prescription and management</td>
</tr>
<tr>
<td></td>
<td>Poor assessment results in no referral to other medical team members, reducing clients functional and rehabilitation potential</td>
</tr>
<tr>
<td>Risk</td>
<td>Potential Consequences</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Inappropriate device selection                                       | Device does not provide client with the optimal outcome  
Client unable to adequately function at home and meet ADLs, therefore increasing the need for carers and/or admission to care facility  
Device does not immobilise limb therefore resulting in further medical intervention, such as fracture fixation  
Development of muscular damage, such as contractures  
Re-hospitalisation for further rehabilitation  
Home and/or community based falls  
Reduced client confidence associated with falls  
Fractures and subsequent hospitalisation due to falls  
Death  
Legal action taken |
| Inappropriate selection of materials and components in the design of the device | Provision of an inferior device which may not achieve its required functional goal  
Client unable to adequately function at home and meet ADLs, therefore increasing the need for carers and/or committing to care facility  
Superficial injury due to material selection, increasing risk of infection, skin breakdown etc  
Re-hospitalisation for further rehabilitation  
Home and/or community based falls  
Reduced client confidence associated with falls  
Fractures and subsequent hospitalisation due to falls  
Development of muscular damage, such as contractures  
Death  
Legal action taken |
### Table 3: Risks to clients when Orthotist/Prosthetists inappropriately manufacture a device

<table>
<thead>
<tr>
<th>Risk</th>
<th>Potential Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate selection of materials</td>
<td>Device does not provide client with the optimal outcome</td>
</tr>
<tr>
<td></td>
<td>Adverse reaction to materials requiring medical intervention and period of non-use of device</td>
</tr>
<tr>
<td></td>
<td>Superficial injury due to material selection, increasing risk of infection, skin breakdown etc</td>
</tr>
<tr>
<td></td>
<td>Materials failure resulting in home and/or community based falls</td>
</tr>
<tr>
<td></td>
<td>Reduced client confidence associated with falls</td>
</tr>
<tr>
<td></td>
<td>Fractures and subsequent hospitalisation due to falls</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Inappropriate manufacturing technique</td>
<td>Provision of an inferior device which is prone to failure</td>
</tr>
<tr>
<td></td>
<td>Failure of device resulting in hand/or community based falls and/or superficial damage to limb segments</td>
</tr>
<tr>
<td></td>
<td>Re-hospitalisation for further rehabilitation</td>
</tr>
<tr>
<td></td>
<td>Reduced client confidence associated with falls</td>
</tr>
<tr>
<td></td>
<td>Fractures and subsequent hospitalisation due to falls</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Failure to observe the technical recommendations of components and/or the specifications of materials</td>
<td>Provision of an inferior device which may not achieve its required functional goal</td>
</tr>
<tr>
<td></td>
<td>Provision of a device with high failure risk, increasing the potential for home and/or community based falls and superficial limb damage</td>
</tr>
<tr>
<td></td>
<td>Re-hospitalisation for further rehabilitation</td>
</tr>
<tr>
<td></td>
<td>Reduced client confidence associated with falls</td>
</tr>
<tr>
<td></td>
<td>Fractures and subsequent hospitalisation due to falls</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
</tbody>
</table>
Table 4: Risks to clients when Orthotist/Prosthetists fail to observe regulations and protocols

<table>
<thead>
<tr>
<th>Risk</th>
<th>Potential Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to observe “single use” protocols</td>
<td>Provision of a contaminated device, exposing to client to infections such as MRSA or VRE</td>
</tr>
<tr>
<td>Re-issue of a device or component which is designated as “single use only”</td>
<td>Provision of a contaminated device exposing client to bacterial infection</td>
</tr>
<tr>
<td></td>
<td>Hospitalisation associated with infection</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Provision of device based on availability not assessment, therefore not meeting manufacturer’s recommended prescription guidelines</td>
<td>Provision of an ineffectual device that does not meet client requirements</td>
</tr>
<tr>
<td></td>
<td>Refer risks Table Two – Inappropriate device selection</td>
</tr>
<tr>
<td>Inappropriate recycling of components</td>
<td>Provision of a worn and unreliable component which is prone to failure</td>
</tr>
<tr>
<td></td>
<td>Failure of device resulting in home and/or community based falls and/or superficial damage to limb segments</td>
</tr>
<tr>
<td></td>
<td>Reduced client confidence associated with falls</td>
</tr>
<tr>
<td></td>
<td>Fractures and subsequent hospitalisation due to falls</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
<tr>
<td>Failure to observe universal precautions</td>
<td>Inappropriate handling of a device contaminated, such as with MRSA and/or VRE</td>
</tr>
<tr>
<td></td>
<td>Cross-contamination of clients due to device handling</td>
</tr>
<tr>
<td></td>
<td>Hospitalisation associated with infection</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>Legal action taken</td>
</tr>
</tbody>
</table>
Table 5: Risks to clients when Orthotist/Prosthetists communicate poorly with the client and/or treating team

<table>
<thead>
<tr>
<th>Risk</th>
<th>Potential Consequences</th>
</tr>
</thead>
</table>
| Provision of insufficient or unclear information to client on the wear regime and use of a device | Client inappropriately dons the device, increasing potential for falls and superficial injury  
Client inappropriately wears the device, compromising the rehabilitation progress and outcome  
Home and/or community based falls  
Reduced client confidence associated with falls  
Fractures and subsequent hospitalisation due to falls  
Development of muscular damage, such as contractures  
Superficial injury and associated medical interventions  
Death  
Legal action taken |
| Inefffectual communication with the client’s treating team           | Device is removed from the treatment program due to a misunderstanding regarding its design and function  
Device is inappropriately integrated into the treatment program, increasing the potential for falls and development of pressure areas from a poor wear regime |
## 7. APPENDIX TWO

Procedures or activities undertaken by health practitioners which carry risk

### Table 6: Types of procedures or activities undertaken by Orthotist/Prosthetists which carry risk

<table>
<thead>
<tr>
<th>Risk</th>
<th>Example of Orthotist/Prosthetist related activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. “Putting an instrument, hand or finger into a body cavity . . . or into an artificial opening”.</td>
<td>Orthotist/Prosthetists are regularly required to probe artificial openings of the body, such as sinuses, ulcers, suture openings, fissures and open wounds. An example would include the measuring and protecting of an open ulcer in preparation for plaster casting of the area, with post-cast cleaning required.</td>
</tr>
<tr>
<td>3. “Application of a hazardous form of energy . . . nerve conduction . . . electromagnetic waves . . .”</td>
<td>Orthotist/Prosthetists use myoelectrics and neurotronics (Functional Electrical Stimulation), being the application of personal nerve stimulators in order to trigger a neural response. Examples of this include the WalkAide and BioNess.</td>
</tr>
<tr>
<td>4. “Procedures below the dermis, mucous membrane . . .”</td>
<td>Orthotist/Prosthetists specialise in Halo Thoracic Brace application in which a medical practitioner cuts the dermis for the Orthotist to locate and screw halo pins into the skull under the correct tension.</td>
</tr>
<tr>
<td>10. “Setting or casting a fracture or bone or reducing a dislocated joint”.</td>
<td>Orthotist/Prosthetists set fractures and bones within acute hospital settings, using soft bracing or plaster/fiberglass cast techniques. They are also involved in limb immobilisation of for muscle lengthening, muscle repair and post-surgical treatment.</td>
</tr>
<tr>
<td>12. “Treatment that commonly occurs without any other persons present”</td>
<td>Orthotist/Prosthetists are allied health professionals who work as part of a multidisciplinary team, but which perform their activities in isolation. These activities may include assessment, casting, fitting and review of patients and their equipment.</td>
</tr>
<tr>
<td>13. “Treatment that commonly requires patients to disrobe”.</td>
<td>Patients receiving orthotic and prosthetic services are commonly required to have plaster casts taken. For spinal orthoses, this involves a full trunk cast in which the patient wears only underwear. Trans-femoral prosthetic casting involves disrobing of the lower half of the body. Plaster is applied to the trans-femoral residuum, the perineum and gluteal region. This process involves palpation of the ramus and ischial tuberosity, usually covered by underwear, which is slipped aside during this process.</td>
</tr>
</tbody>
</table>

Source: Adapted from the Regulated Health Professions Act 1991 (Ontario)
8. **APPENDIX THREE**

The case of Robert John ROBERTS, Summary of Coroners Report, Tasmania, 2006

Summary of Coroner’s Report

In April 2005 Mr Roberts, aged 72 years, presented to the Emergency Department of the Launceston General Hospital following a fall whereby he struck his head. His plain cervical spine radiographs and CT scan revealed an unstable fracture of the first cervical vertebra. In light of his medical co-morbidities, especially end-stage kidney failure, it was decided that he should be admitted under the care of the Renal Medicine Unit.

His radiological films were reviewed with the Orthopaedic Surgeon team, and it was decided that he be fitted with a Halo brace as a form of external stabilization of the cervical fracture, in the place of the hard collar, and instead of more invasive internal surgical stabilization. The coroners reports states that “experienced staff were made available for the application of the Halo brace on April 8......”, which included an experienced Plaster and Halo Jacket Technician, Head Surgeon, and two Orthopaedic Registrars. It is worth noting that the appropriately trained health professional for application of a halo head ring, screws and jacket is an Orthotist, who was not involved in the treatment of this patient.

The halo application was complicated by Mr Roberts being agitated, having a severe sloping forehead, swelling around his eyebrows consistent with his Cushingoid (moon face) appearance and oedema from lying on his back for the previous 48 hours. Because of these factors at the time of pin insertion, it was difficult to clearly assess the distance between skin and bone. A halo ring was applied in the standard fashion with local anaesthetic to the pin sites. Four pin sites were used and the actual torque measure of each pin is not reported, however the left frontal pin was ‘odd’ at the time and the bone was reported as ‘soft’ and therefore less tension was applied to that pin in comparison with the others. The frontal pins were inserted in the standard position of just above the outer third of the eyebrow.

Several doctors reviewed the client on the ward and later in ICU. The pins were torqued on numerous occasions to 8Nm for all pins except the left frontal pin, which is reported as torqued to 6Nm. The doctors report that the left frontal pin was only ever turned “a few times”. Treatment of the deceased relating to his respiratory issues and acute kidney failure continued, with him showing signs of improvement so 49 hours after his admission to the Intensive Care Unit his intravenous sedation was ceased. However the patient continued in a poor state of conscious despite no sedation for 48 hours. Therefore a CT scan was conducted which “......revealed evidence of a large left-sided intra-ventricular and temporofrontal haemorrhage with surrounding oedema (bleed in the brain and into internal cavities). There was clear evidence of a pin penetration on the left frontal side, extending several millimetres into the intracranial cavity”.

There was no bed available in Hobart or Melbourne intensive care units for repair of the dural hole on that day. Over the next 24 hours it became clear that transfer and possible neurosurgical intervention would be unlikely to change his overall prognosis. It was elected not to transfer him after full discussions with the family. The patient continued to receive palliative care until he passed away on the 21st of April 2005.
The State Forensic Pathologist conducted a post mortem examination and states “... this gentleman clearly had a pin penetration of the left frontal bone at the time of insertion and application of the halo splint. There are several reasons associated with that and most are related to patient circumstances:

Facial swelling from steroid dependence and generalised oedema

Soft bone

Agitation

Renal failure

Osteoporosis

Low sloping forehead”.

The AOPA’s clinical comments regarding this case:

The Coroner in this case fails to comment on whether a Plaster Technician is the appropriately trained professional to assist an Orthopaedic Team with Halo pin and jacket application. A Specialist Orthotist is typically the health professional responsible for checking the tension, applying and monitoring the superstructure and re-tensioning the halo pins (and monitoring the pin turns so as to avoid perforation). Consensus knowledge amongst Specialist Orthotists suggests that best practice in paediatrics and in the presence of osteoporosis is to use more pins sites with lower pin tensions (typically ranging between 2 and 6Nm). In the case of osteoporotic bone, pins are usually tensioned to a maximum of 6 Nm, with the tension for normal presentation between 6 and 10 Nm. In this case, the treatment and application of a halo brace was not completed by a Specialist Orthotist, and therefore the halo application was not appropriately customised according to this patient’s clinical presentation. Nor does it appear that the halo management was monitored with the required regimen that Orthotists typically abide by, in monitoring and limiting the degree to which halo pins are tensioned, in order to avoid potential pin perforation.
9. LETTERS OF SUPPORT

Practitioner Regulation Subcommittee
National Health Ministers’ Advisory Council
9th December, 2010

To whom it may concern

The National Centre for Prosthetics and Orthotics (NCPO) at La Trobe University is the only tertiary training facility for Orthotist/Prosthetists in Australia. As Head of the Department, I am writing in support of the submission by Mr. Richard Dyson-Holland, President of The Australian Orthotic Prosthetic Association Inc., regarding the inclusion of Orthotist/Prosthetists in the National Registration and Accreditation Scheme, and subsequent regulation of the profession.

The NCPO has sole responsibility for the training of the orthotic and prosthetic workforce in Australia. The school works alongside the orthotic and prosthetic profession to ensure that this training meets current profession requirements. With only 35 graduates per year, there is a responsibility to produce practitioners who meet current workforce demands and ensure public protection through a high standard of clinical competency.

National registration is an important step in the continued development of the orthotic and prosthetic profession, and a necessary step to guarantee public safety. NCPO graduates are eligible for membership to The Australian Orthotic Prosthetic Association Inc., however without mandatory membership there is no formal commitment of the entire profession to ongoing professional development and learning post-tertiary education.

Of greater concern to the NCPO and for public safety, is the inability to prevent unqualified individuals from practicing. The NCPO provides a world-renowned education program, with graduates being well regarded and highly sought after for clinical and academic positions internationally. The NCPO can guarantee the standard of graduates, but due to the lack of a supportive regulation framework and restriction of title, this does not ensure a workforce standard within Australia.

Therefore, as Head of Department at the National Centre for Prosthetics and Orthotics, and with support from academic and teaching staff, I strongly endorse this submission for national registration of Orthotist/Prosthetists.

Yours sincerely

Rowan English
Head of Department,
National Centre for Prosthetics and Orthotics
La Trobe University, Melbourne, Victoria.
TOWARDS A SAFE AND SUSTAINABLE ORTHOTIC AND PROSTHETIC WORKFORCE

Australian Health Professional Registration Association

27th November, 2010

Dear Sir/Madam,

The recent introduction of the national registration scheme for health professionals includes a large number of allied health professionals. The prosthetists and orthotists have not been included in this single national registration scheme until this stage.

Being a medical specialist working in rehabilitation, I have been working together with allied health in various multidisciplinary teams over a period of approximately 25 years. One of the major categories of patients that I treat are persons who have had an amputation and require fitting and ongoing management of their prosthesis. There are also a significant number of patients who require orthotists in treating their symptoms or maximizing their function. Prostheses and orthoses are made by professionals who have undergone tertiary, usually university training in prosthetics and orthotics and have subsequently become registered practitioners. Usually, that means they are members of AOPA, the Australian Orthotic and Prosthetic Association.

The training of prosthetists and orthotists and their role in a multidisciplinary team is equivalent to that of other allied health professionals. They have a unique area of expertise which is essential for the management of patients who require prosthesis or orthoses.

In view of the mobility of health professionals, the need throughout Australia for prosthetists and orthotists and an acknowledgment of the importance of high standards and quality of practitioners throughout the country, it would be beneficial if prosthetists and orthotists were also part of a single national registration scheme. This would enhance ability to ensure equity of access and service provision throughout Australia for prosthetic and orthotic services.

I would be grateful if you would give this matter due consideration and consider the request by AOPA to become part of the single national registration scheme favourably.

Yours faithfully,

Associate Professor Friedbert Kohler, Conjoint Associate Professor UNSW,

Director of Rehabilitation Medicine, Sydney South West Area Health Service
Director of Rehabilitation Medicine, Braeside, Liverpool and Fairfield Hospitals
Director of Medical Services, Braeside Hospital
Senior Staff Specialist in Rehabilitation Medicine
President ISPO ANMS (International Society for Prosthetics and Orthotics, Australian National Member Society)
10. REFERENCE LIST


Submission from:
The Australian Orthotic Prosthetic Association Inc., representing the Australian orthotic and prosthetic profession

To the Practitioner Regulation Subcommittee:

For inclusion in the National Registration and Accreditation Scheme for health professionals