A pilot study evaluating topical negative pressure using V1STA® technology

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Abstract

A number of recent research articles have shown that negative pressure wound therapy (NPWT) is effective in healing a wide range of complex wounds. This form of therapy helps expedite wound healing mainly by the removal of wound exudate, bacterial reduction as well as encouraging wound contraction. A pilot study was conducted to evaluate the clinical efficacy and cost-effectiveness of NPWT using the V1STA® wound vacuum system (Smith & Nephew) across three surgical areas. This technology uses a special gauze-based wound interface instead of the medical grade sponge. This evaluation, which consisted of 20 patients with chronic or surgical wounds, included objective wound measurement at each dressing change to track wound healing rates. The complexity of wounds included compromised graft site (1), diabetic foot ulcers (8), dehisced surgical wounds (5), orthopaedic wounds (5) and necrotising fasciitis (1). This study has demonstrated that positive outcomes were obtained at cost savings of almost 30%, compared with the alternative NPWT. Furthermore, this mode of delivery not only was a lot easier to apply but was relatively pain-free to remove the old dressings.

Introduction

Negative pressure wound therapy (NPWT) was pioneered in the 1980s and 1990s in a series of clinical studies in Russia, Europe and the United States of America. It has filled a niche in managing large and complex wounds and has gained acceptance as a useful tool in achieving definitive wound closure.

NPWT is based on a concept of a closed wound management system that has three components: a comfortable, permeable and compressible wound filler, an airtight wound cover and a suction device to create a vacuum. A variety of filler has been used, including domes, gauze and foam [1-8]. The first commercially available NPWT system was the vacuum assisted closure (**VAC®**) system, which was brought into the market by KCI Medical Incorporated (Kinetic Concepts Inc.) which achieved FDA approval in 1995. The **VAC®** system uses foam as the wound filler and, until recently, was the only available product on the Australian market.

Smith & Nephew has recently marketed an alternative NPWT system called V1STA®. This product utilises the Cheriker-Jeter technique, where gauze is used as the wound filler. Our unit has extensive experience using the foam-based VAC® system and there are some concerns expressed in regard to the cost of the dressings, the fact that if left longer than the recommended duration that granulation tissue can adhere to the foam and some dressing pain issues.

In this study, the aim was to evaluate the efficacy of a gauze filler with negative pressure wound therapy on a variety of wound types and compare it with our experiences using a foam-based system.

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Method

A prospective clinical case study was conducted at the Royal Adelaide Hospital (RAH) surgical wards on patients admitted between June and October 2008. As this study was considered more observational and there was no likelihood that the gathering of this information could have resulted in harm or inconvenience to the patients, the Hospital Ethics Committee was made aware of this project. The inclusion criteria included vascular, plastic surgery, gynaecology and orthopaedic patients that had large cutaneous soft tissue defects that were not amenable to immediate wound closure. The exclusion criteria included patients with poor compliance or those who had this therapy discontinued for medical reasons. The decision on whether to use NPWT was made by the treating surgeon.

All wounds were managed by a single nurse wound consultant under the supervision of the admitting surgeon. All patients

were treated with the V1STA® gauze-based negative pressure therapy system. Following surgical debridement, the wound bed was cleaned with saline and the AMD Kerlix™ gauze was moistened with saline and wrapped around the suction drain, which was inserted into the wound bed. The wound was then packed to the level of the defect. Occasionally, Cuticerin, a non-adherent, impregnated gauze, was used as an interface between the wound bed and the gauze. A clear, occlusive dressing was then used to seal the wound. The suction drain was then connected to the V1STA® vacuum pump. A negative pressure suction of between -40 to -200mmHg (generally -80mmHg) was then set using the continuous mode. An intermittent mode was also available but not used for this trial. The dressings were changed at 2- to 3-day intervals. Once the wound was judged by the treating surgeon to be ready, definitive closure was performed.

Data collected included wound surface area and depth using the VISITRAK® (Smith & Nephew) wound measurement system. Measurement and photographs were taken prior to therapy, at weekly intervals and at the cessation of NPWT. Issues of pain and use of analgesia were evaluated using a pain scale (0=no pain, 10=extreme pain) especially on application and on removal of dressings. This information was documented in the patients' case notes.

Quantitative data was collected over the treatment duration including digital wound planimetry using the VISITRAK® Wound Measurement Tracing Grid (Smith & Nephew) prior to the application of therapy, at each dressing change and at the conclusion of NPWT. The VISITRAK® grid is a trilaminate of two transparent films, which allows clinicians to record the outline of the wound margin and to calculate the area of the wound using VISITRAK® Digital. It is used to record valuable information such as wound area, the percentage area of the wound that is non-viable and viable and, most importantly, the change in wound area. Furthermore, wound depth can be measured using the calibrated sterile wound probe. Moore [15] maintains that if the islands of epithelial tissue have been traced, their area can be subtracted from the total area.

Feedback from clinicians who used this therapy and patients' experience of this device was collated using both questionnaires and patient stories.

Results

Twenty patients used the V1STA® gauze-based negative pressure system. Excluded were the five orthopaedic patients who had V1STA® used mainly for compound fractures of the lower legs (following motor bike accidents) that were too dirty to close in the first instance, thus surgical debridement,

sometimes multiple, were required to clean the wound bed followed by NPWT use (Table 1). In the majority of instances the wound would be closed within a couple of days as delayed primary closures (DPC). The NPWT in this instance was used to reduce the oedema, reduce the bacterial load and thus improve the vascular bed. As this mode of therapy worked as well as the foam alternative, some trauma surgeons favoured its use.

The keenness of the clinicians from the various surgical disciplines for favouring the use of the V1STA® was the fact that the application was a lot easier and involved less complicated cutting of the dressing to fit differing wound areas. The time saved was a major positive factor. Furthermore, the removal of the dressings was easier due to the interface dressing used.

Table 1. Patient demographics.

Males	15
Females	5
Average age (years)	66
Average weight (kg)	81
Smokers	5

Issues of pain and use of analgesia as well as ease of application and removal of the gauze were evaluated. Clinical photography was also used to convey the outcomes. A questionnaire was used to obtain feedback from clinicians who used this therapy and patients' experience of this new therapy device was collated using both questionnaires and patient stories. The application of this mode of therapy on challenging body areas are also discussed in this paper.

Some case studies using NPWT (V1STA®)

In the plastic surgery or gynaecology units the cases were quite challenging. The first case was a 61-year-old emaciated individual who had a radical removal of a squamous cell carcinoma from his neck and the defect covered with bilateral pedicle pectoral major flaps. The secondary defects were covered by split skin grafts harvested from his thigh. The donor site healed well, but the grafted site became rather moist and colonised and there were concerns of graft failure on day 3 post-grafting. V1STA® was applied with the wound interface protected with Cuticerin, a smooth acetate fabric with a defined mesh size and a hydrophobic coating, which is based on petrolatum, paraffin and wool wax alcohol. A bridging technique was used to ensure both wounds were treated together. The graft-take improved by 17% in 5 days, despite his poor general condition (Figure 1).

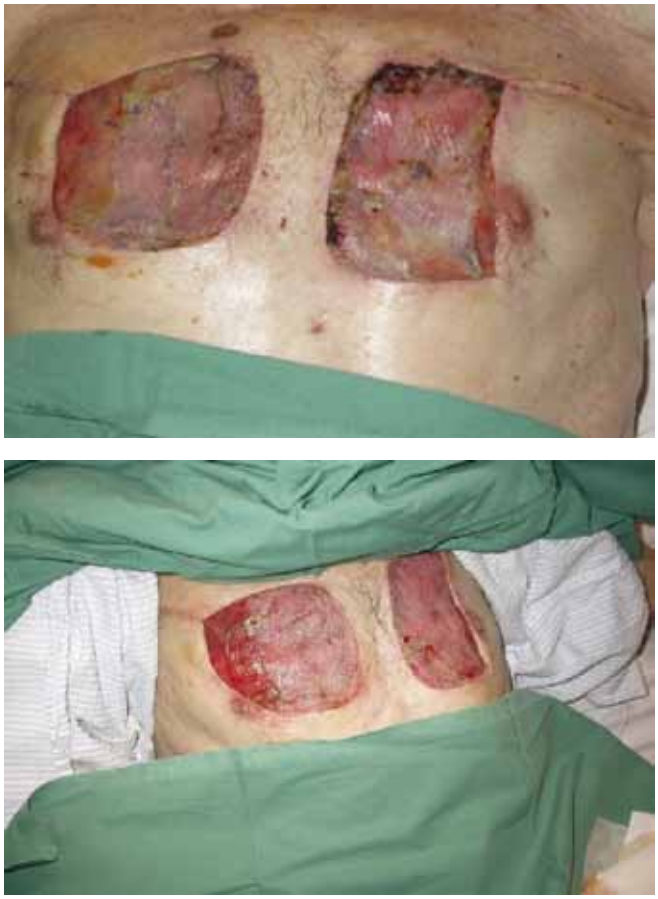
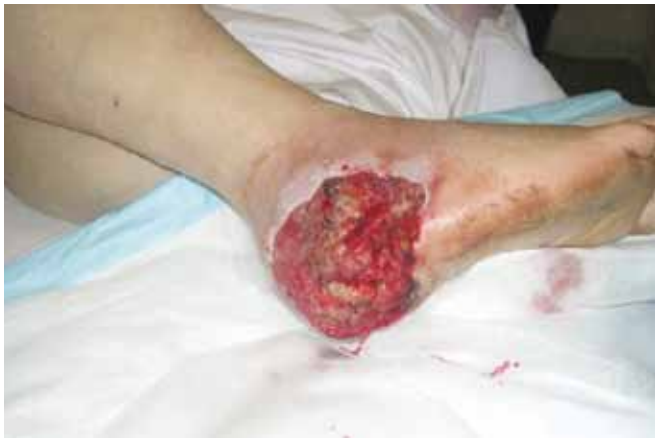


Figure 1. Case 1 – Pectoral area with split skin graft, 17% reduction in 5/7.

Another interesting case was a 54-year-old vascular patient with a diabetic foot ulcer on her heel. She refused a below knee amputation and was referred to the plastic surgery team for an opinion. V1STA® therapy was commenced post-debridement of the wound. She had 25.3% wound reduction in 18 days. A meshed graft (hand-fenestrated) was applied to the granulating bed and V1STA® NPWT was applied over the skin graft. This was discontinued on day 5 and her graft take was successful. She was discharged home with district nurse follow-up in the community (Figure 2).

The third case involved a 55-year-old gynaecology patient who had a wound dehiscence post-abdominal hysterectomy. The sutures were removed and V1STA® was applied to the wound. The contraction and healing was quite remarkable, achieving a healing rate of 20% in just 9 days. She had her wound primarily closed and was discharged home (Figure 3).

The fourth case was a 62-year-old lady with necrotising fasciitis involving her lower abdominal area close to her genitalia. The contours and folds of her body coupled with the geographical location of the wound provided the clinicians quite a challenge to obtain a seal for the V1STA® to work (Figure 4).



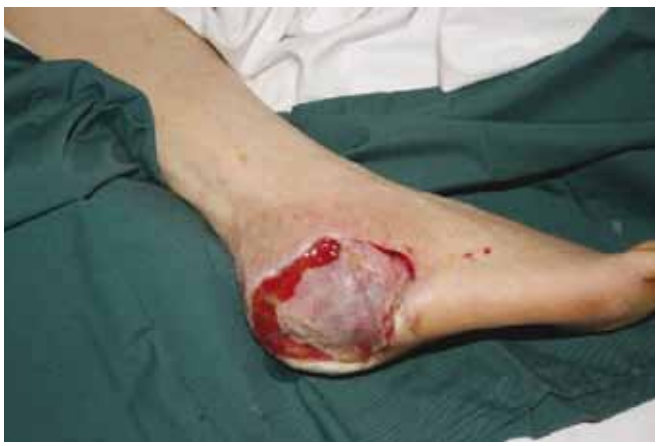
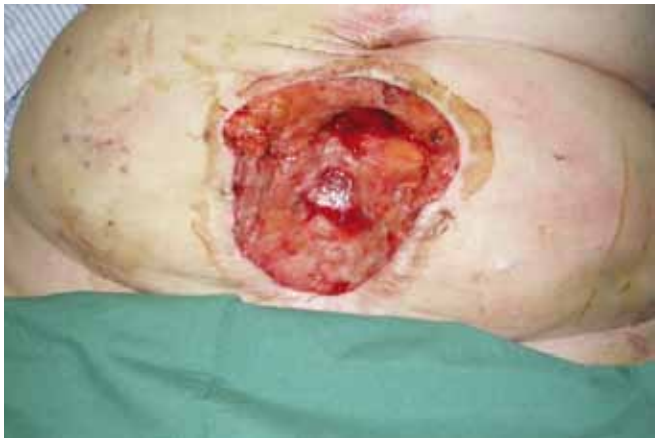


Figure 2. Case 2 – Diabetic foot ulcer, 25.3% reduction in 38/7.



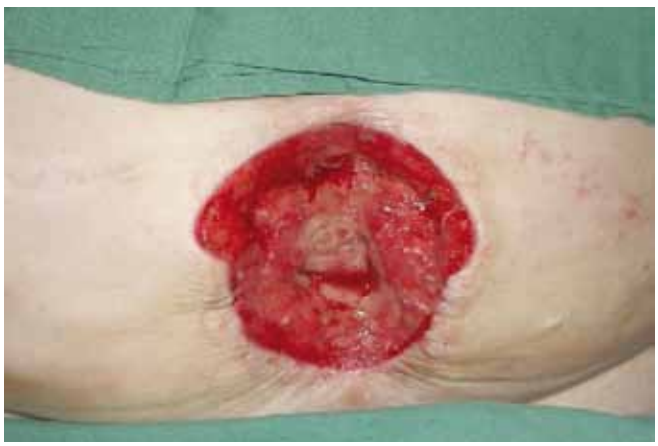


Figure 3. Case 3 – Wound dehiscence, 20.6% reduction in 9/7.

Due to the complexity of her condition, post-surgical debridement, she was initially nursed in the intensive care unit (ICU). This lady had the experience of both the sponge (KCI) dressings initially in ICU followed by the use of the V1STA® when discharged from ICU to the ward. Her testimony about both technologies was obtained by interview. She claimed that the sponge dressings used were "cumbersome and heavy" and far more restrictive of her movements in bed. Furthermore, the removal of the sponge felt like someone was "pulling her stomach out". She claimed that the gauze (V1STA®) was more comfortable, especially at night and the removal of the dressing was relatively pain-free, allowing a significant reduction in her use of analgesia. The use of the V1STA® yielded 17% wound healing in just 5 days. Her wound was surgically debrided and a meshed skin graft was used to cover this large area. She was discharged home following good graft take.

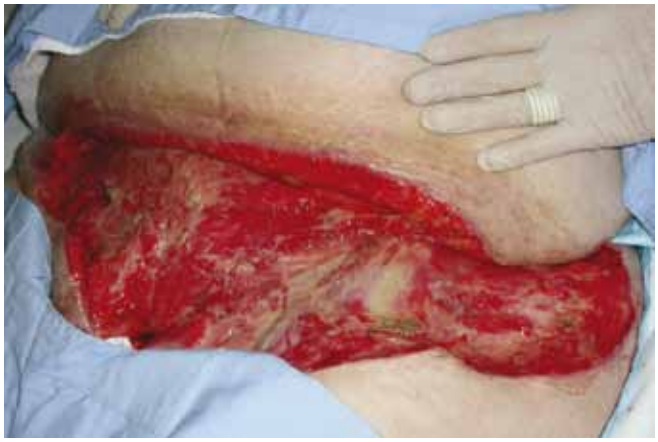
The fifth case was a wound dehiscence on the right groin following an aortofemoral graft on an 85-year-old lady. She was a type 2 diabetic, anaemic and had MRSA in her wound bed. Post-debridement and use of the V1STA® resulted in a 60.7 % wound reduction in 18 days (Figure 5).

Clinical benchmarks

Our aim was to achieve 15-18% decrease in wound surface area in problematic or chronic wounds each month. Flanagan [12] suggests that a percentage area reduction, rather than absolute area reduction, is the best way of predicting healing rates. He claims that a reduction of between 20-40% in the first 2 to 4 weeks is likely to be a reliable predictor to healing [11, 12]. Likewise, Stacey [16] reiterates that percentage area reduction has been identified as a useful parameter for assessing a chronic wound's response to treatment.

Discussion

From our case studies we noted that we exceeded these benchmarks (Table 2) and further we also had positive affirmations from patients that the dressing application and removal were of minimal discomfort to them. The emotional and physical experiences of the patients were obtained by interview and the use of questionnaires. There were no issues with dressing adherence and most patients used minimal analgesia, which may be attributable to the actual structure of the two dressings.



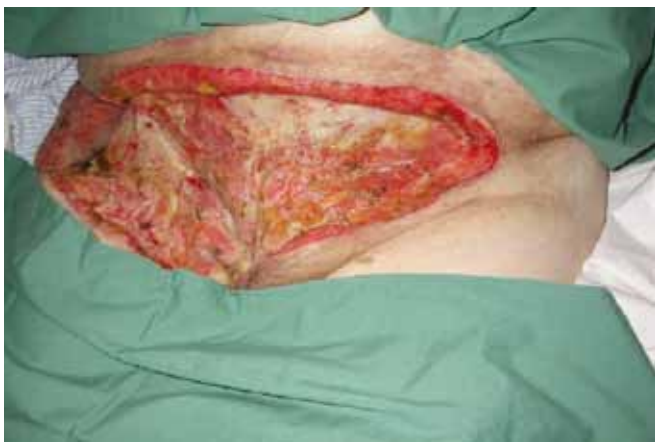


Figure 4. Case 4 – Necrotising fasciitis, 44.9% reduction in 15/7.

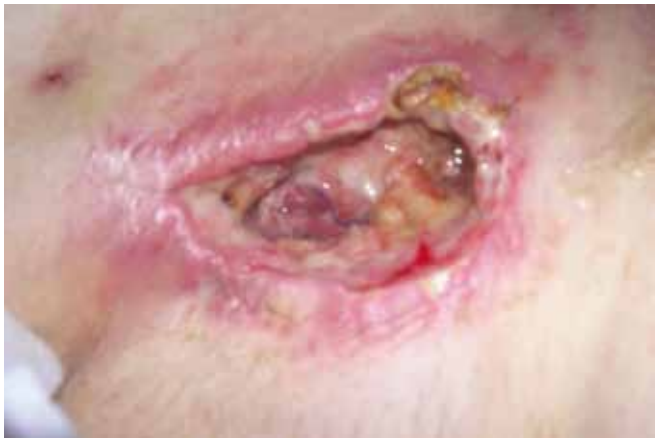


Figure 5. Case 5 – Wound dehiscence, 60.7% reduction in 18/7.

Table 2: Clinical outcomes (Using* VISITRAK® *technology)*

Wound area at commencement of NPWT	65.6 cm^2
Wound area on completion of NPWT	18.6 cm^2
Treatment time	15 days

*Average *excludes the five orthopaedic cases, where the aim of using NPWT was to enable a closed system/wound until return to the OR, whereby delayed secondary closure/free flap/split skin graft then took place.*

VAC® GranuFoam™ vs Kerlix™ gauze

The VAC® GranuFoam™ allows for microscopic vessels from the granulation tissue to grow into the interstices of the foam. This usually occurs if the foam is accidentally left on the wound for longer that the recommended duration. This is not always very painful to remove but there are instances where patients had to return to the theatre for foam dressings to be removed. The use of the AMD Kerlix™ gauze, on the other hand, does not adhere to the wound bed, despite being left on the wound for longer than 2 days. This may be due to the weave of the Kerlix™ gauze as well as the occasional use of the interface dressing used (Cuticerin) (Figure 6).

Staff who used the V1STA® gauze-based NPWT found it was easy to apply, saved a lot of time and was not distressing for their patients. The author feels that the dissemination of this information to other clinicians will prompt further randomised controlled studies by other academics to confirm or refute these findings.

No one treatment modality in wound care will facilitate 100% healing and quantitative data remains the gold standard for ensuring the appropriate commencement and cessation of all treatments to provide wound closure. The VISITRAK® technology was invaluable in enabling us to demonstrate these outcomes in an objective context. The other positive is that the V1STA® can be used for both deep and shallow wounds with good outcomes. The improvement in patients' outcomes was imperative and the cost benefits give this mode of treatment more appeal.

Conclusion

Harding *et al.* assert that in our current economic climate, where resources are limited, clinical efficacy alone is not always sufficient to justify the use of a product [13]. The results of this evaluation using the V1STA® wound vacuum system across the three surgical areas has provided very

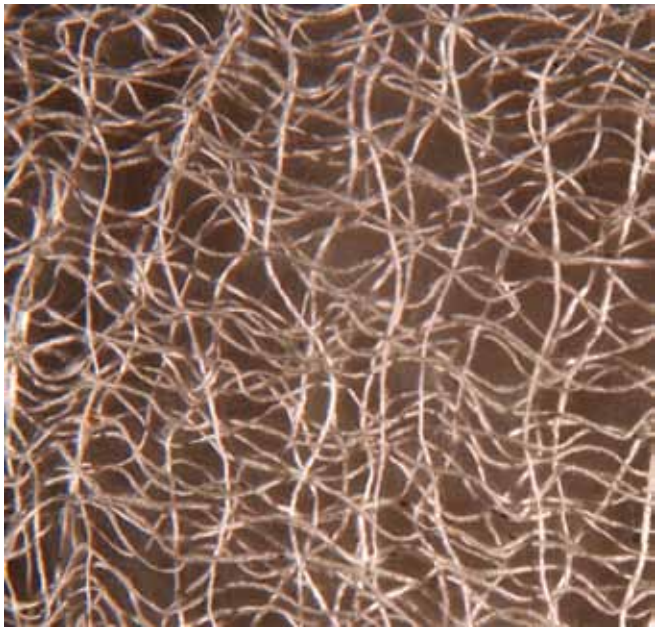


Figure 6a. Kerlix™ gauze x10 magnification.

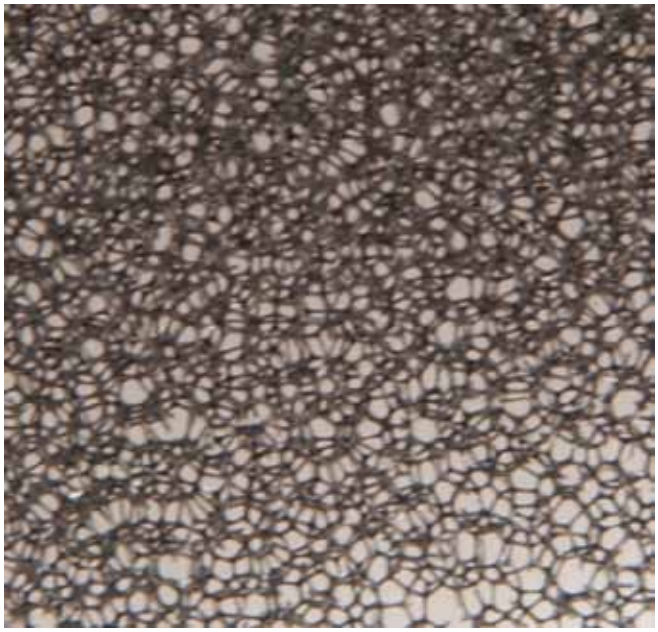


Figure 6b. VAC® GranuFoam™ x10 magnification.

promising preliminary data and confirm significant wound improvement with cost reduction. If we compare the current rental rate of the foam alternative (VAC®) in the market now and what the rental rate of V1STA® will be coupled with the cost of dressings and the canisters required there is a saving of approximately 30%. This does not take into consideration the savings that can be made by the use of less analgesia by patients using V1STA® during this pilot study.

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Conflict of interest statement

The authors state that while Smith & Nephew Inc supplied the topical negative machines used within this study, the RAH purchased all consumables. They have no conflict of interest with the outcome of this study.

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Australian Wound Management Research Foundation Research Grants 2010

Call for Applications

The Australian Wound Management Research Foundation (AWMRF) is calling for applications for Research Grants that will be awarded in 2010. The AWMRF encourages and supports high quality research into any field or discipline related to wounds or wound healing.

The Grants are for projects that are of one year duration, with an expectation that they will commence in the later half of 2010 and will be completed by the middle of 2011.

The Grants are considered to be seeding grants which will enable researchers to gain preliminary information that can be used to prepare applications for large scale grants from different funding bodies. The Foundation will allocate funds up to a maximum budget of $10,000 for any individual Research Project. The number of awards and the amounts that are allocated will be dependent on the quality of the applications that are received.

Applications will be received from January 18, 2010 and will close on March 5, 2010. Applications will be considered by a Scientific Advisory Committee of the AWMRF. The successful applications will be announced at the AWMA National Conference in Perth, March 24-27, 2010.

Further details about the grants, the application process and guidelines for the application can be obtained from the AWMA website at www.awma.com.au or by contacting Professor Michael Stacey at the University of Western Australia, School of Surgery, Fremantle Hospital, Fremantle, Western Australia, 6160 – Fax (08) 94312623, Phone (08) 94312500, email michael.stacey@uwa.edu.au