

The early studies

 **smith&nephew**

PICO[®]

Single-Use
Negative Pressure
Wound Therapy System



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1. Forward by Professor Donald Hudson and Dr Kevin Adams at Academy of Plastic Surgery, Claremont, South Africa and Dr Adriaan van Huyssteen at Panorama Mediclinic, Panorama, South Africa

“We have been closely involved with Negative Pressure Wound Therapy (NPWT) for many years, have tested and indeed helped to develop a number of systems for use on our patients in Cape Town.

Combining the clinical effectiveness of NPWT with the known benefits of advanced wound care dressings always seemed to be an ideal solution for some patients, especially those at high risk in the critical days following surgery. Recently we were very pleased to have been able to examine the performance of just such a prototype device on a number of patients in our clinics.

This booklet describes 12 recent case histories using PICO[®], a single use NPWT system provided by Smith & Nephew, beginning with some background on NPWT, before describing PICO and moving on to the clinical cases. We hope that you will agree that PICO opens up some very interesting possibilities in treating many kinds of small to medium sized wounds in both hospital and outpatient settings.”

2. The evolution of Negative Pressure Wound Therapy

Over the past 15 years, Negative Pressure Wound Therapy, (NPWT), has provided clinicians with a powerful new resource to manage complex wounds. Here is a broad summary of the known effects of NPWT:

- Promotion of a closed moist environment. (Morykwas et al., 1997)
- Reduction of tissue edema. (Kamolz et al., 2004)
- Contraction of the wound edges. (Malmsjö et al., 2009)
- Mechanical stimulation of the wound bed. (Saxena et al., 2004)
- Alteration of blood flow at the wound edges. (Wackenfors et al., 2004)
- Stimulation of angiogenesis. (Greene et al., 2006)
- Formation of granulation tissue. (Armstrong and Lavery 2005)
- Physical splinting of grafts. (Llanos et al., 2006); and incisional wounds (Gomoll et al., 2006)

Much research is being done in many of these fields, and every year we get a better overall understanding of the mechanisms of action, role and future potential of NPWT (see Malmsjö and Borgquist 2010, Henderson et al., 2010 for some easy to understand reviews).

For some of the most challenging wounds, NPWT is becoming a first line therapy - but what about wounds which are still important but of a less serious nature? Are the costs of therapy or the restrictions on the daily activities of patients justified for less severe wounds? PICO^o is a new simplified NPWT system that combines the associated benefits of NPWT with the simplicity of an advanced wound care dressing for small to medium size wounds with low to moderate levels of exudate.



3. What is PICO^o?

PICO is a single-use NPWT system. A small, discrete pump, powered by two AA lithium batteries, is coupled to an advanced dressing which negates the need for a bulky canister. In suitable wounds it may be applied in just a few minutes.

The dressing consists of:

1. A silicone adhesive wound contact layer which helps establish an effective seal, yet is gentle on the periwound area.
2. An airlock layer that distributes the negative pressure across the dressing.
3. A super absorbent layer which moves exudate away from the wound and surrounding skin and initiates the evaporation process.
4. A high rate moisture vapor transmission (MVTR) film which allows a one-way transpiration of the collected exudate vapor and makes a canister redundant.



PICO° is supplied in a pack that can be taken off the shelf when required. It contains a single-use pump, which lasts for seven days, and two individually packed dressings and fixation strips (allowing for the wound to be inspected during those seven days).

The pump is operated through a single orange button. It works with normal lithium AA batteries. While the batteries may be recycled, the pump should be disposed of as non-clinical waste when treatment is finished.

Three lights let you know how PICO is working – a green light which flashes constantly to tell you it is working properly and two amber alarm lights which flash if there is an issue. One indicates an air leak and a second shows that the battery charge is low. The batteries may be replaced within the seven day life of the pump.

The pressure is nominally pre-set at -80mmHg. Research shows that physiological effects are near maximal at this level (Borgquist et al., 2010a; Borgquist et al., 2010b):

A single push of the orange button starts the therapy. If the button is pushed again, the therapy will pause and then will automatically restart after an hour if the button is not pressed again before this time.

There are a number of dressing sizes available. The table below also details the available pad area (taking into account the port area where necessary) to help align the wound size to the appropriate dressing.

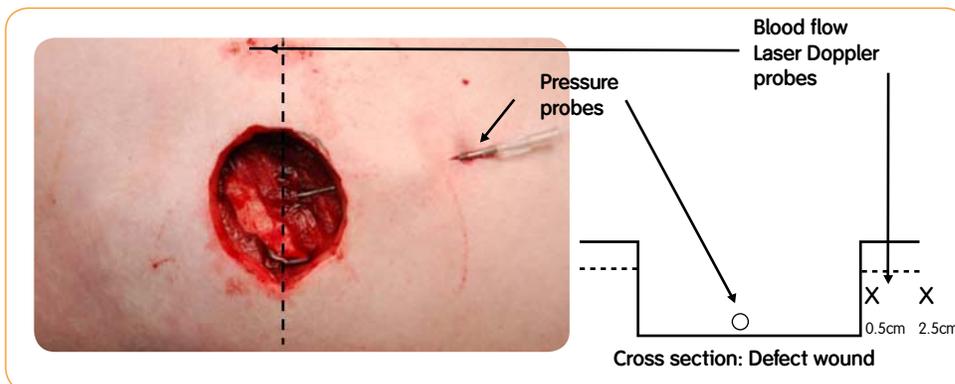
Size (cm)	Size (inches)	Available pad area (cm)	Available pad area (inches)
10 x 20	4 x 8	5 x 10	2 x 4
10 x 30	4 x 12	5 x 20	2 x 8
10 x 40	4 x 16	5 x 30	2 x 12
15 x 15	6 x 6	10 x 10	4 x 4
15 x 20	6 x 8	10 x 15	4 x 6
15 x 30	6 x 12	10 x 25	4 x 10
20 x 20	8 x 8	15 x 15	6 x 6
25 x 25	10 x 10	20 x 20	8 x 8

4. What does research on PICO^o tell us?

At the University of Lund in Sweden, scientists examined whether PICO delivers NPWT in the same manner as traditional devices such as RENASYS^o or VACTM. In making such an assessment they tested three factors which have been established as mechanism of action for NPWT.

- The transmission of negative pressure to the base of the wound. (Malmsjo et al., 2009a)
- Tissue contraction. (Malmsjo et al., 2009a);
- Establishing a characteristic pattern of periwound blood flow. (Morykwas et al., 1997; Borgquist et al., 2010b):

These tests were undertaken in wounds on anaesthetised pigs. Pressure was measured through probes inserted in the base of the wound. Laser Doppler filaments were used to measure blood flow.

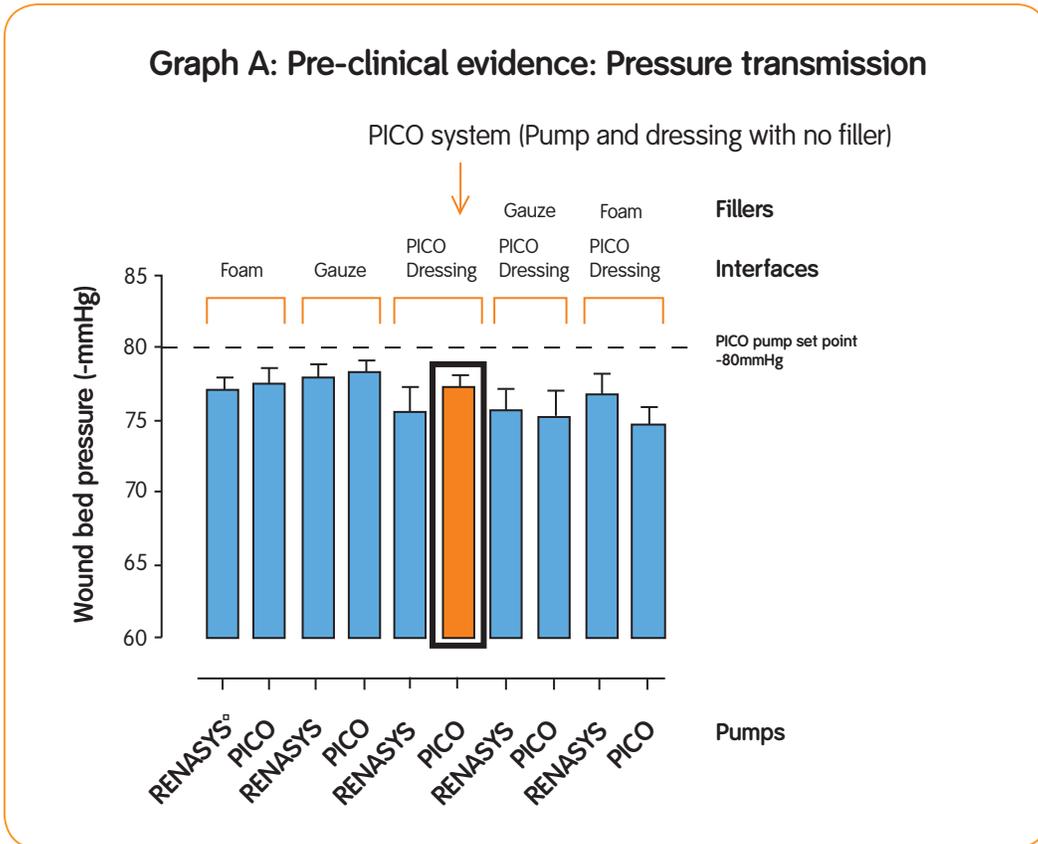


Fresh acute wound, 6cm diameter and 2cm deep with laser Doppler (fine filaments) probes and pressure sensor probes in position. The dashed line indicates the plane of the cross section which appears above each wound. All methods were as reported (Malmsjö et al., 2009a; Borgquist et al., 2010b).

In order to demonstrate that the PICO pump and the PICO dressing operate as conventional NPWT devices, combinations of the PICO pump with or without different fillers and a RENASYS pump (set at -80mmHg) with or without different fillers, were tested alongside the PICO pump and dressing. In PICO the negative pressure has been selected as -80 mmHg since research has shown that both foam and gauze fillers can operate successfully at this pressure and clinical and physiological effects are near maximal (Borgquist et al., 2010a; Borgquist et al., 2010b).

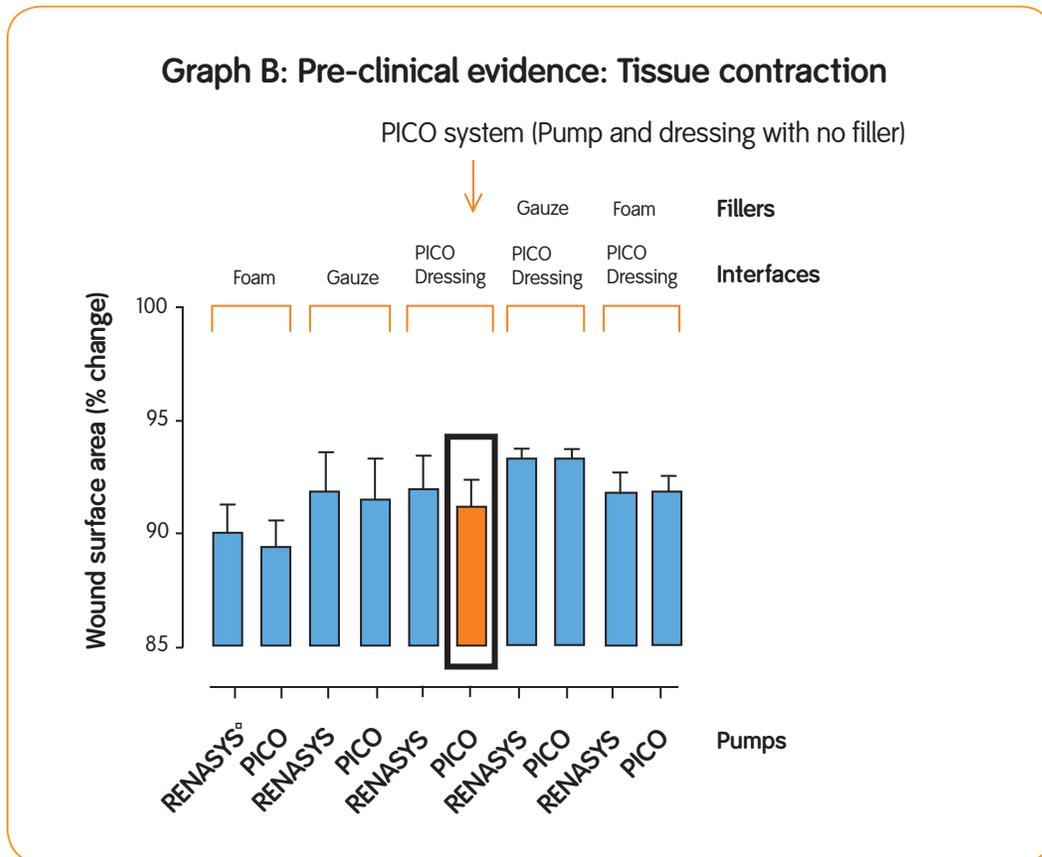
1. Transmission of negative pressure levels at the wound bed

In each combination the pressure levels achieved at the wound bed were virtually identical to the operating set point of the PICO^o pump. This shows that the PICO pump and dressing (orange bar) will operate to deliver specified negative pressure to the wound bed with or without foam and gauze fillers (Graph A).



2. Tissue contraction

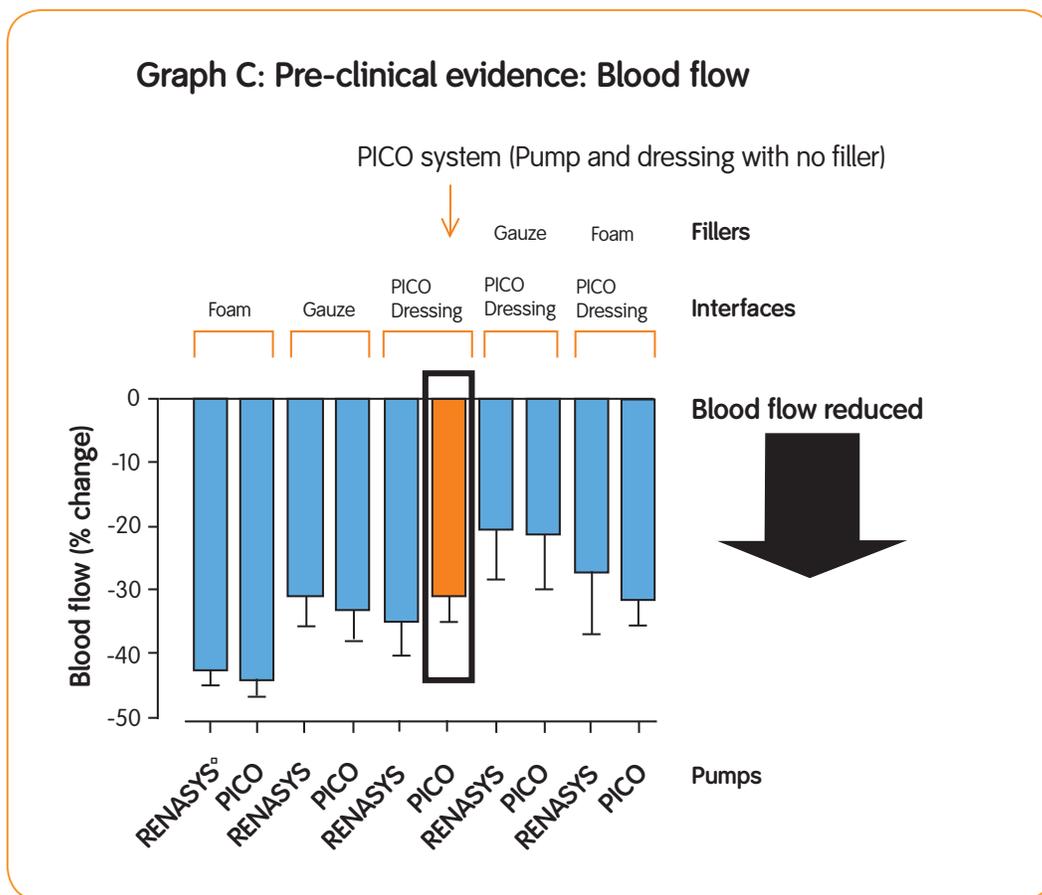
Tissue contraction recorded for the PICO^o pump and dressing is highlighted by the orange bar. In the defect wound, tissue contraction was observed for all pump and dressing combinations including the PICO pump and dressing combination. Slightly greater contraction (90%) was seen with negative pressure applied to foam fillers than with gauze filler (92%) or the PICO pump and dressing (92%). This verifies that PICO delivers tissue contraction comparable with conventional NPWT devices operating on defect wounds (Graph B).



3. Establishing a characteristic pattern of periwound blood flow

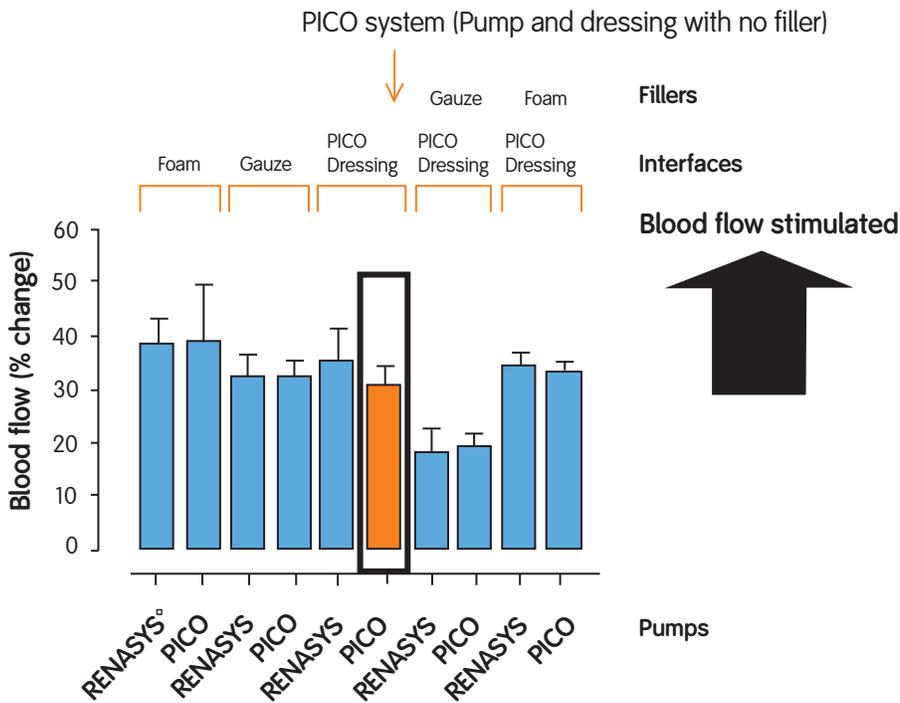
It has been established that with either foam or gauze-based conventional NPWT a characteristic pattern of blood flow is set up after negative pressure is applied to a defect wound. Close (0.5cm) to the wound bed or wound edge, blood flow is reduced. Further away (2.5cm) from the wound bed or wound edge, blood flow is stimulated (Malmsjö et al., 2009a; Malmsjö et al., 2009b; Borgquist et al., 2010b).

Combinations of RENASYS[®] and PICO[®] pumps were used with gauze, foam or PICO dressings on 6cm diameter full thickness wounds. Close to the wound edge (0.5cm) the PICO pump and dressing causes a reduction in blood flow as do all other combinations of NPWT pump and dressing (Graph C).



In contrast, further away from the wound edge (2.5 cm) the PICO^o pump and dressing causes a stimulation in blood flow as do all other combinations of NPWT pump and dressing (Graph D). The PICO pump and dressing operate in an identical fashion to conventional NPWT devices in setting up the same patterns of blood flow. Malmsjö et al., 2009b; Borgquist et al., 2010b).

Graph D: Pre-clinical evidence: Blood flow



The following 12 cases illustrate how treatment with PICO[®] has worked on a variety of wounds including surgical incisions.

Traumatic wound

1. Use of PICO following suture of a dog bite wound

A 30-year-old woman was treated for a dog bite injury on her lower leg. Following surgery her wound measured 7.5cm x 6cm.

The patient was given a PICO system with the 15cm x 20cm dressing, which the surgeon was able to apply in five minutes.

The patient had PICO in place at home for ten days, with just the pump changed on the sixth day. On day ten, the patient stopped taking analgesics and a routine dressing change took place showing that the wound was progressing.

On day fourteen, the treatment ended according to the set protocol, with the wound still progressing well. The patient was given an absorbent dressing and IV3000[®] in order to conclude her treatment.

The clinician commented on the portability and ease of application of PICO on this patient who was treated at home.



Fig 1. The PICO system was applied 4 days after initial suturing due to skin flap necrosis around the edge of the wound



Fig 2. Dressing in place on lower leg post surgery, day 1



Fig 3. Wound after 14 days showing vascularisation through the scar, which the clinician found to be exceptional

Skin Graft

2. Use of PICO^o post burn skin graft to the knee

An 80-year-old man was treated for a non-healing burn on the knee with debridement and a skin graft. The wound measured 15cm x 5cm with moderate levels of exudate. MRSA had been detected on a wound swab, and he had been prescribed systemic antibiotics.

Smith & Nephew's PICO system with the 10cm x 25cm dressing was applied to stabilize the skin graft and absorb the wound exudate. A CUTICERIN^o Wound Contact Layer was applied between the graft and the PICO dressing.

The patient was discharged from the hospital on day two with PICO in place. On day three there was no vacuum and the leak light was flashing, but the problem resolved itself. Treatment with PICO continued until day five, when on assessment, the skin graft had taken and treatment moved on to ACTICOAT^o Flex and a conventional bandage.

The clinician was very satisfied with the PICO dressing performance.



Fig 1. Non-healing burn wound before debridement and application of skin graft



Fig 2. PICO dressing in place over skin graft



Fig 3. Skin graft after removal of PICO dressing on Day 5

Post-surgical wounds

3. Use of PICO^o in a post-surgical wound following breast reconstruction: 1

A 41-year-old woman S/P mastectomy had been receiving treatment for breast cancer. Following radiotherapy, she underwent surgery for breast reconstruction and a tissue expander was inserted.

Smith & Nephew's PICO system with the 30cm x 10cm dressing was applied to deliver NPWT to the incision and manage wound drainage.

Following application of PICO, the patient was allowed to go home with PICO in place and was seen daily as an outpatient from day two as a participant in the study. The pump was changed on day six and the dressing was changed on day eleven.



Fig 1. Post surgical wound following breast reconstruction. The wound measured 15cm in length and 0.5cm in width. Note the closed incision is raised above the level of surrounding skin.



Fig 2. Patient with dressing in place on first assessment (day 1).



Fig 3. Post surgical wound after PICO removal day 11. Note some indentation from the PICO dressing, but otherwise healthy surrounding skin. The surgical incision is closed, there is no exudate and the incision is flat. Compare with the tunnelled IV site wound of same age which remains raised.

Post-surgical wounds

4. Use of PICO[®] on a post-surgical wound following breast reconstruction: 2

A 27-year-old woman had a surgical wound measuring 14.1cm x 0.1cm following a skin sparing mastectomy and immediate prosthetic breast reconstruction. The PICO system was applied.

On the first day after application, the pump and dressing were changed. The wound was already progressing to closure. The patient was discharged from hospital on day 5.

A third PICO system was applied on day six, and treatment continued until day eleven when the wound was seen to be closed and treatment with PICO was ended.

Overall the surgeon was very satisfied with the performance of the dressing.



Fig 1. Wound immediately following breast reconstruction surgery



Fig 2. PICO dressing in place on day 7



Fig 3. Wound on day 14, wound closure noted on day 11

Post-surgical wounds

5. Use of PICO[®] following incisional hernia repair

A 52-year-old man with diverticular disease and an incisional hernia had a colectomy and surgical repair of his hernia. The wound measured 26cm x 5cm x 0.1cm and was closed by suture.

A PICO system with the 10cm x 30cm dressing was applied.

Treatment continued for six days. At the routine first dressing change, the wound was closed with no exudate or infection present. Treatment with PICO was discontinued at this point.

Overall the clinicians were satisfied and found PICO to perform better than they might have expected advanced wound dressings to in this instance.



Fig 1. Post surgical wound on 52-year-old male before application of PICO. The clinicians noted a wide undermining of skin and tight closure of the abdominal wall.

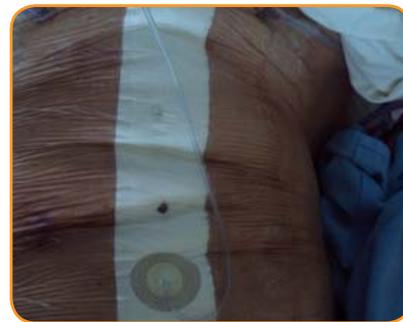


Fig 2. PICO dressing over incisional hernia after first application



Fig 3. Wound closed after removal of PICO dressing on day 6

Post-surgical wounds

6. Use of PICO[®] post hip implant surgical wound: 1

A 53-year-old man suffering from osteoarthritis had surgery for a hip implant. His wound, closed by suture and Steri-Strips™, measured 17.5cm x 0.5cm.

He was given a PICO system with the dressing measuring 10cm x 30cm.

A routine dressing change was performed on day three. At this point, his wound was progressing to closure with no infection and light exudate.

The patient remained comfortable, although on day five, some bruising was noted around the lower aspect of the dressing, which remained for a few days.

At the routine dressing change on day ten, the wound was found to be closed.

Overall the clinician was very satisfied with the treatment.



Fig 1. Hip wound of 53 year old man immediately after surgery



Fig 2 a and 2 b. Wound on day 3, before and after new dressing



Fig 3. Post -surgical hip wound closed on day 10

Post-surgical wounds

7. Use of PICO[®] following hip implant: 2

This 52-year-old woman with osteoarthritis had surgery for a hip implant. Her wound measured 15.5cm x 0.2cm and was closed with a suture and Steri-Strips[™].

A surgeon and assistant took just three minutes to apply the PICO system, using the 10cm x 25cm dressing in the operating room.

Treatment continued uneventfully for six days, throughout which the patient was comfortable.

At the routine dressing change on day seven, the wound was seen to be progressing to closure with healthy surrounding tissue and no infection. A new PICO dressing was applied by the nurse in just two minutes.

At the next routine dressing change on day ten, the wound was found to be closed.

The clinician estimated that the wound had closed three days earlier than might have been expected with an advanced wound care dressing.



Fig 1. Wound immediately following hip implant



Fig 2. PICO dressing in position on day 2



Fig 3. Wound closed after dressing removal on day 10

Post-surgical wounds

8. Use of PICO^o following hip implant: 3

A 65-year-old woman with osteoarthritis, hypertension, and Type II diabetes had surgery for a hip implant.

After surgery, her wound was closed with a suture and Steri-StripsTM. She had a PICO system applied and remained in hospital for five days before she was discharged.

The PICO system was changed on day seven. The wound was progressing well, with no exudate or infection, and a new dressing was placed over the wound in just three minutes.

At the next routine dressing change on day nine, the wound was seen to be closed and treatment with PICO was discontinued.

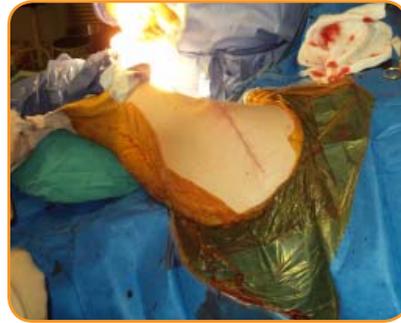


Fig 1. Hip implant wound on 65-year-old woman immediately after surgery



Fig 2. PICO in place over hip on day 4



Fig 3. Wound progressing to closure on day 7.

Post-surgical wounds

9. Use of PICO^o following hip implant: 4

Following a hip implant for this 66-year-old man, a PICO system with the 10cm x 30cm dressing was easily applied in the operating room.

The dressing was changed on day two due to high levels of exudate. Upon removal the wound was seen to be progressing and a new dressing was applied.

The patient was walking comfortably by day three, and was able to go home on day seven. His routine dressing change that day showed further wound progression. However, the patient requested his treatment with PICO to be discontinued as he was leaving the country. As his wound was at this point almost healed, the clinician agreed that no further treatment with negative pressure was required and he was moved to OPSITE^o Post-Op.

Overall, the clinician was very satisfied with the treatment, considering it to be superior to what might have been anticipated with advanced wound dressings.



Fig 1. Hip wound of 66-year-old man immediately after surgery



Fig 2. Wound progressing on day 2



Fig 3. Wound appearance, still progressing to closure, at end of treatment with PICO on day 7

Post-surgical wounds

10. Use of PICO[®] following knee implant: 1

A 77-year-old man, suffering from hypertension and osteoarthritis, had surgery for a knee implant. His wound was closed with sutures.

The patient was given a PICO system with the 10cm x 30cm dressing in the operating room.

After one day, the dressing needed changing. However, the wound was already seen to be progressing to closure at this point.

On day three, moderate exudate levels were noted. The dressing remained intact and continued to deliver NPWT.

The routine dressing change on day six showed the wound to be progressing to closure. The surrounding skin appeared healthy and intact.

At the next routine dressing change on day thirteen, the wound was found to be closed.



Fig 1. 77-year-old male patient after suturing of knee wound in the operating theatre



Fig 2. PICO in place over knee on day 4 showing exudate on the lower part of the dressing



Fig 3. Wound closed at dressing change on day 13

Post-surgical wounds

11. Use of PICO[®] following knee implant: 2

A 48-year-old woman was treated with PICO after knee implant surgery.

Her dressing was easy to apply and treatment continued uneventfully until her routine dressing change on day six, where her wound was seen to be progressing well.

On day ten, the dressing was changed and the wound was found to be closed and no further treatment was needed.

The clinician commented that PICO had a superior healing speed to that expected of advanced wound dressings in this case.



Fig 1. Knee immediately post surgery



Fig 2. Knee wound at dressing change on day 6



Fig 3. Knee wound at dressing change on day 10

Post-surgical wounds

12. Use of PICO[®] after revision of knee replacement

A 61-year-old man had surgery for a knee implant revision.

The wound measuring 23cm x 0.1cm, had been closed with a suture fixed with Steri-Strips[™]. His wound had light exudate and was not clinically infected.

A PICO system with the 10cm x 30cm dressing was applied in the operating room, without difficulties. Treatment continued normally for five days, with the patient able to go home on day three. On day five, a small amount of exudate at the base and middle of the dressing was noted. But at the routine dressing change on day six, the wound was shown to be progressing to closure.

On day seven, the patient mentioned that the dressing felt tighter than it had previously. At the routine dressing change on day ten, the patient reported a mild pain on dressing removal. The wound was seen to be closed at this point.

Overall the clinician was very satisfied with PICO, commenting that it provided fast wound healing and good management of exudate in comparison with advanced wound dressings.



Fig 1. Knee immediately post surgery with tourniquet in place



Fig 2. Wound at dressing change on day 6



Fig 3. Day 10, wound is almost completely healed.

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- A prospective, open, non-comparative, multi-centre study to evaluate the functionality and dressing performance of a new negative pressure enhanced dressing (NPED) in acute wounds.

With over 150 years of experience in advanced wound care, Smith & Nephew is an industry leader providing innovative solutions to meet the needs of chronic, acute and traumatic wounds across all care settings.

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