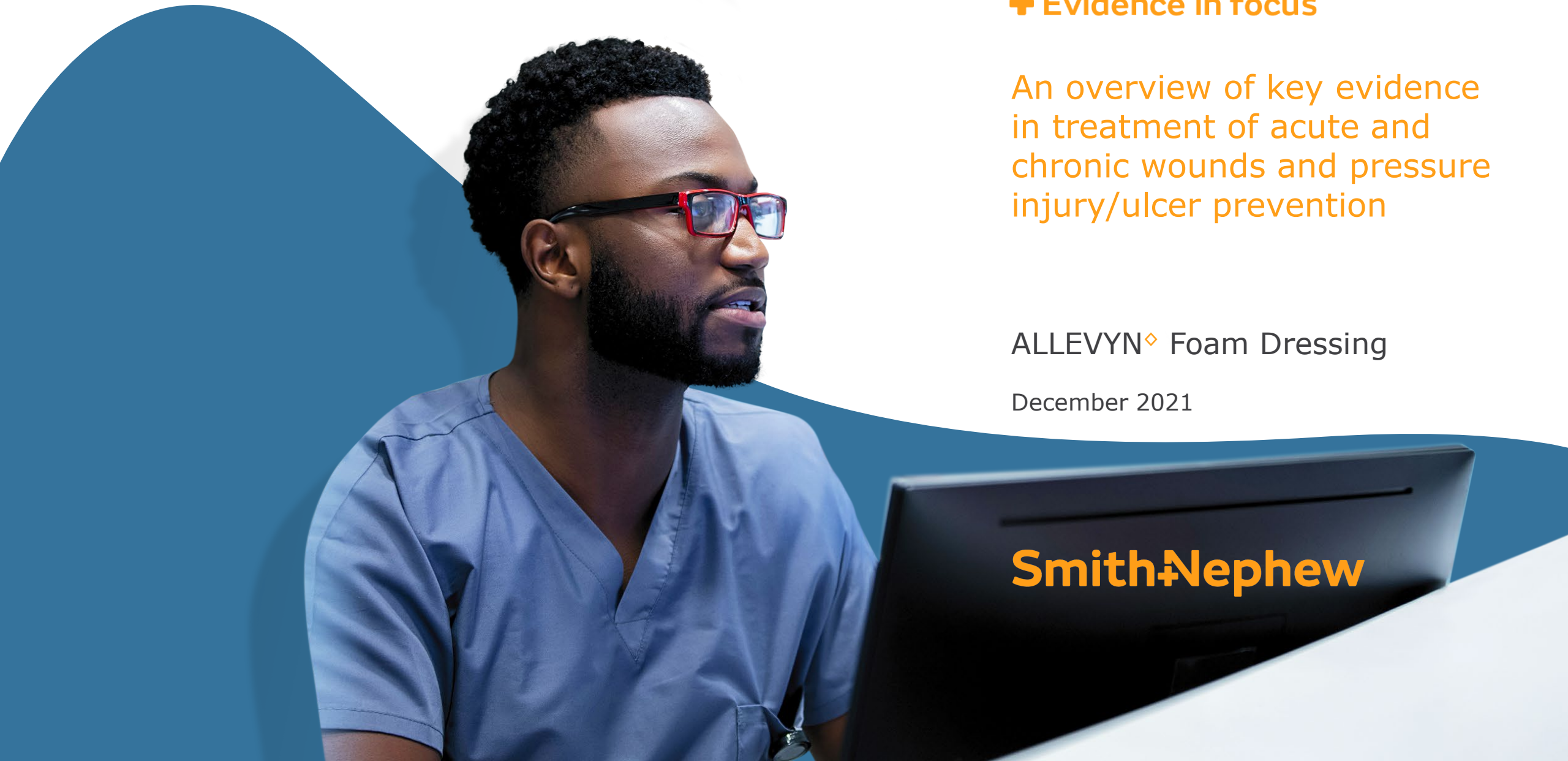


Evidence in focus

An overview of key evidence in treatment of acute and chronic wounds and pressure injury/ulcer prevention

ALLEVYN◇ Foam Dressing

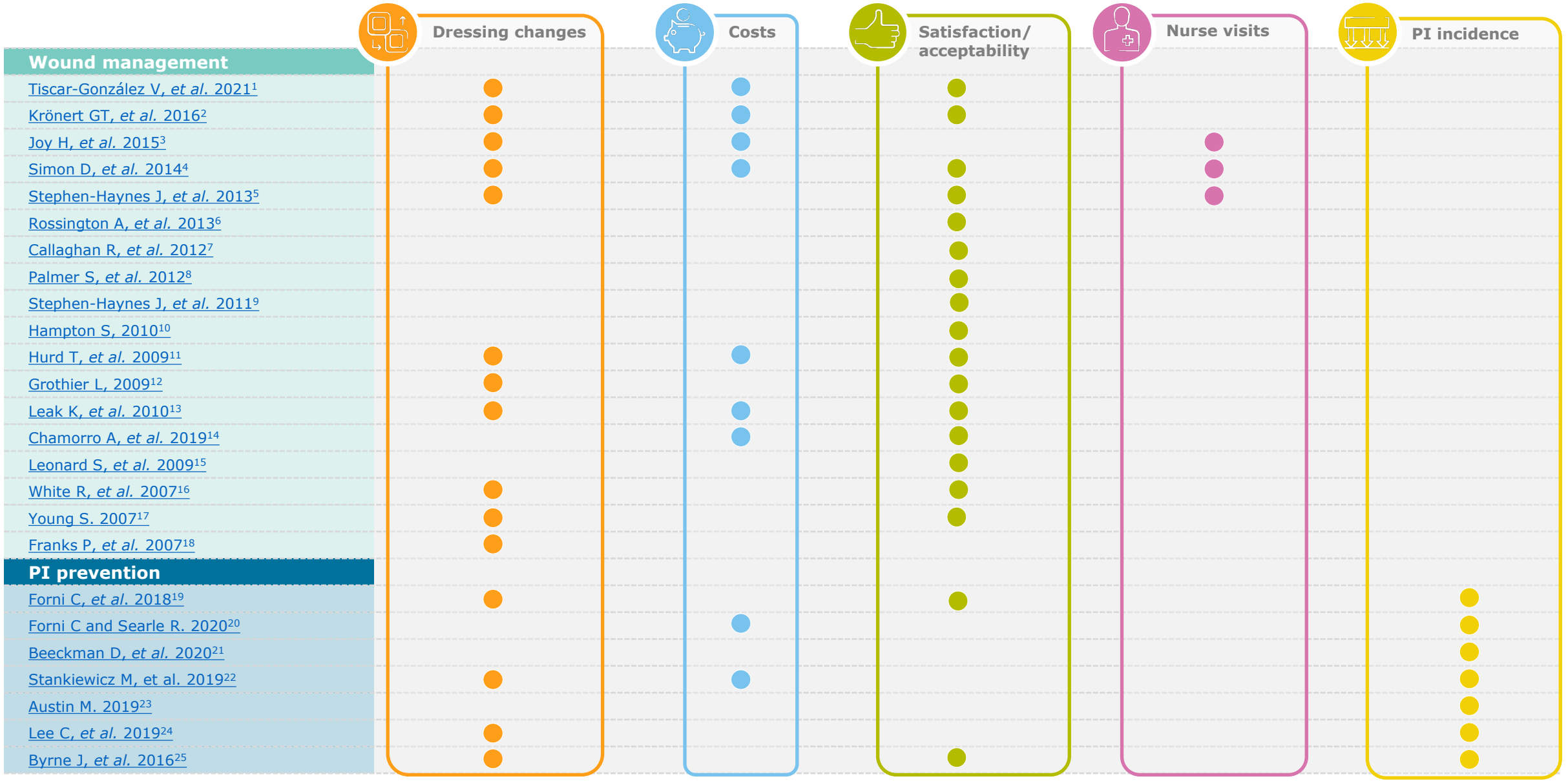
December 2021

Smith+Nephew

Abbreviations

Abbreviation	Full description
DFU	Diabetic foot ulcer
HAPI/HAPU	Hospital-acquired pressure injury/hospital-acquired pressure ulcer
HCP	Healthcare professional
ICU	Intensive care unit
ITT	Intention-to-treat
NHS	National Health Service
PI/PU	Pressure injury/pressure ulcer
PIP	Pressure injury prevention
VLU	Venous leg ulcer

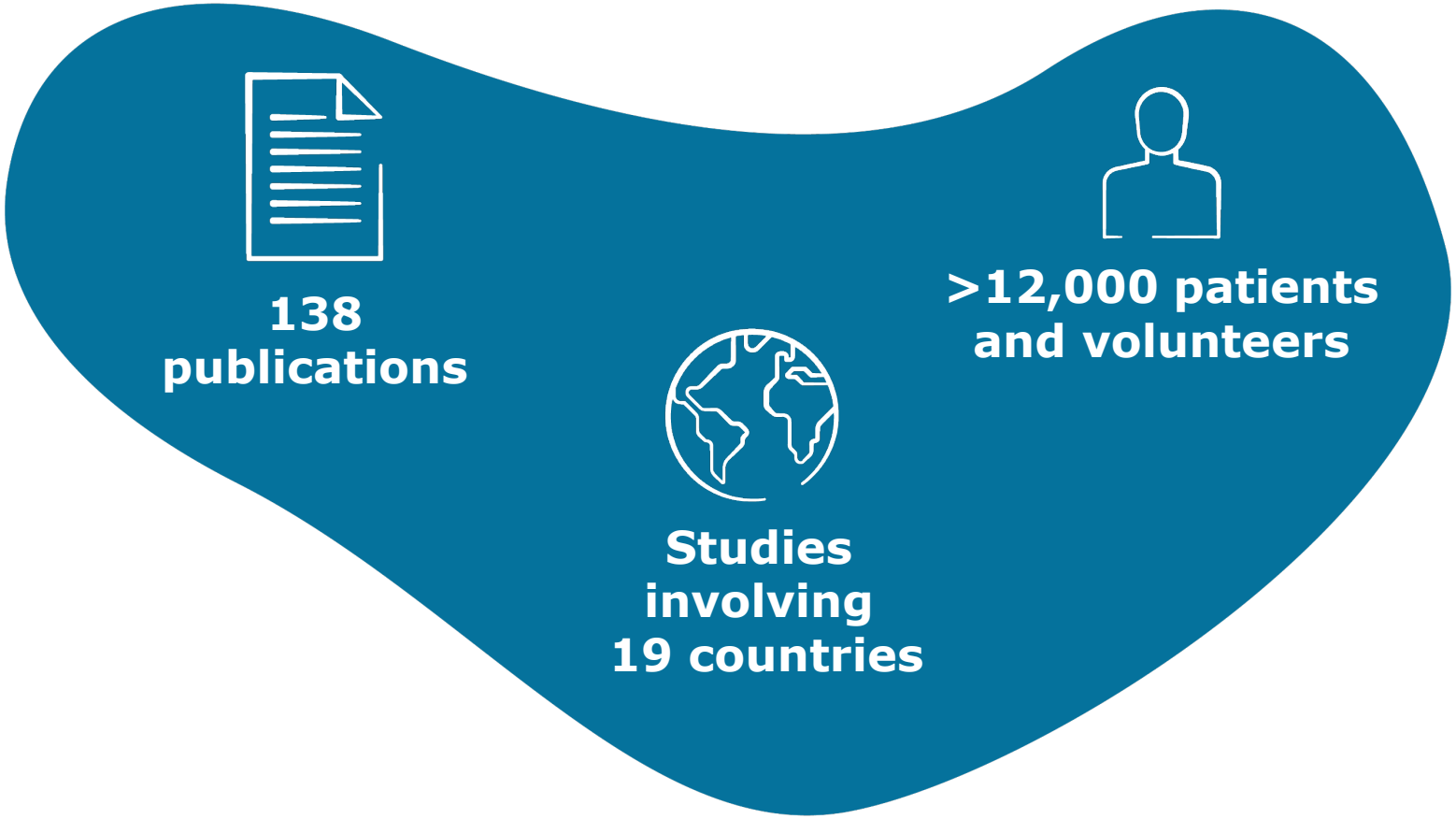
Contents: wound management and PI prevention



Overview of evidence for ALLEVYN◇ Foam Dressing

The aim of this resource is to summarise some key studies supporting the use of ALLEVYN Foam Dressing in wound management and pressure injury (PI) prevention

Although we have selected some key studies to highlight, there is a comprehensive evidence base supporting the use of ALLEVYN Wound Dressings including:[26]

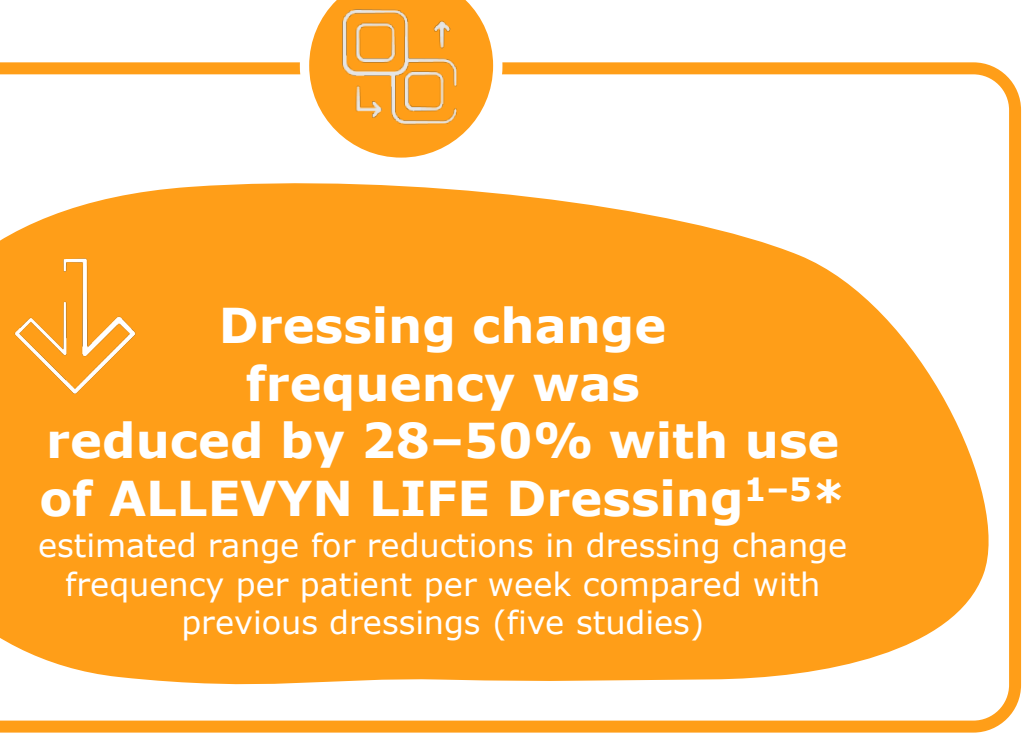


Evidence overview for **dressing change frequency** in wound management studies

Reducing dressing change frequency is one of three key cost drivers that can help to improve efficiency in wound care centres:[27]

1. **Dressing change frequency**
2. **Time to heal a wound**
3. **Incidence of complications**

There are several studies that evaluated dressing performance with ALLEVYN◇ Wound Dressings[1–5,7,11–13,16–18]



*Results from Simon D, *et al.* are calculated based on wounds with ≥3 dressing changes per week

Evidence overview for **costs** in wound management studies

- Wound management is a substantial burden to healthcare systems[28]
- Most costs associated with wound management are incurred in the community where the majority of wounds are managed[28]
- Reducing the cost per dressing per patient could offer savings for healthcare systems and reduce the financial burden of wound management

>£8 billion
estimated cost to the UK NHS for wound management in 2017/18[28]

There are several studies that evaluated costs using the ALLEVYN◇ Wound Dressings[1–4,11,13,14]

Costs were reduced by 23–64% with use of ALLEVYN LIFE Dressing[1–4]*
estimated range in reduction of dressing cost per patient per week compared with previous dressings (four studies)

*Results from Simon D, *et al.* are calculated based on wounds with ≥3 dressing changes per week

Evidence overview for **patient satisfaction** in wound management studies

Wounds and wound management have a major impact on the lives of many patients:

- Wounds are associated with pain, malodour, leakage and restrictions of daily activities[29]
- Painful dressing changes and low dressing absorbency can impact quality of life and leave patients dissatisfied[1]
- Enhancing patient satisfaction with their dressing is important to improving quality of life and wound healing[30]

1.5 to 2.0 million people
were estimated to be living with a chronic wound across Europe[27]

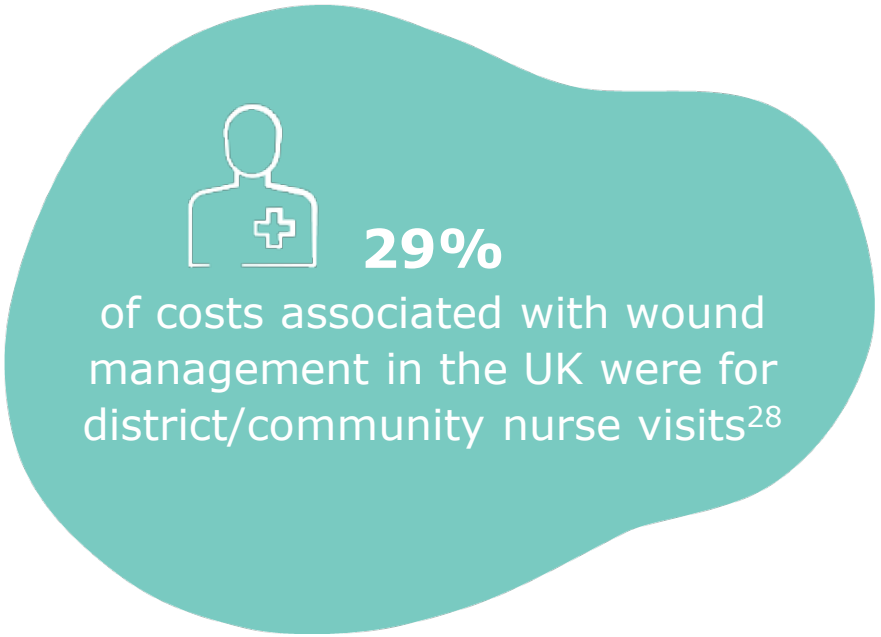
Several studies have evaluated clinician acceptability and/or patient satisfaction[1,2,4–17] using ALLEVYN◇ Wound Dressings

73–83%
patient satisfaction with use of ALLEVYN LIFE Dressing[1,6]
estimated range in patient satisfaction (two studies)

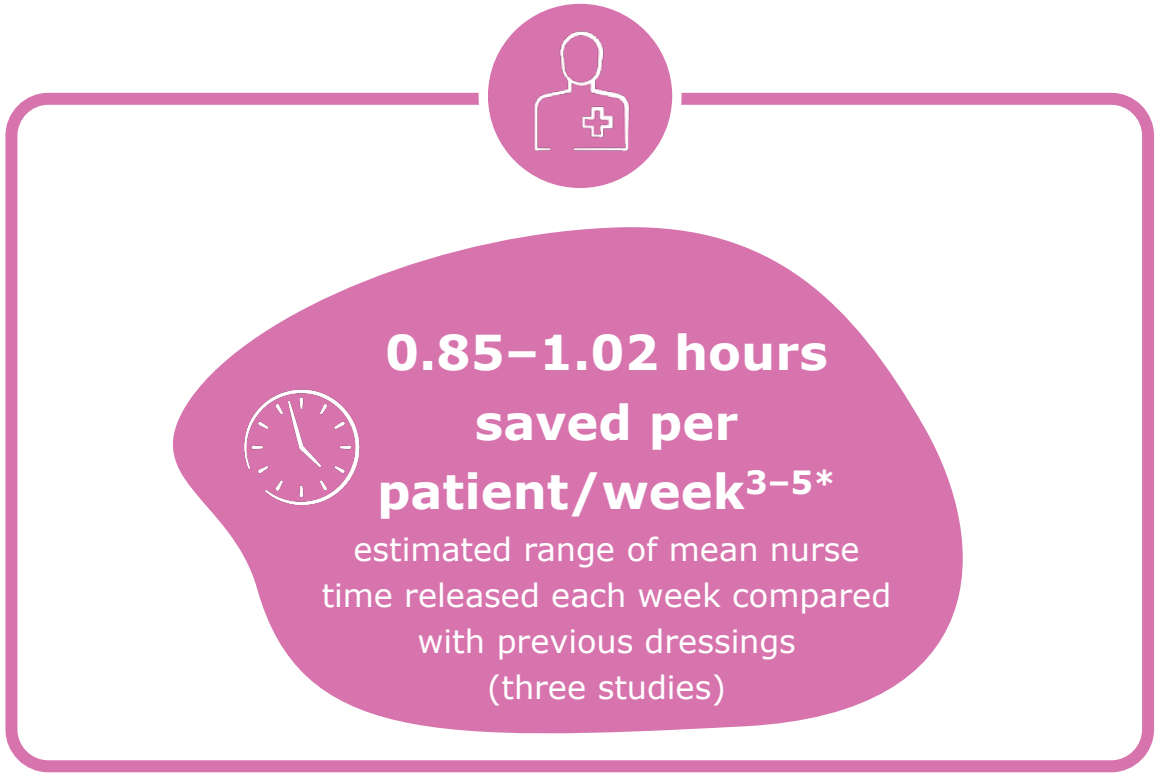
Evidence overview for **nurse visits** in wound management studies

Many wounds are managed in the community by GPs, practice nurses, district/community nurses and healthcare assistants[28]

Reducing the number of nurse visits could help to reduce the healthcare resource burden of wound management



Three studies of ALLEVYN◇ LIFE Dressing have evaluated nurse visits[3–5]



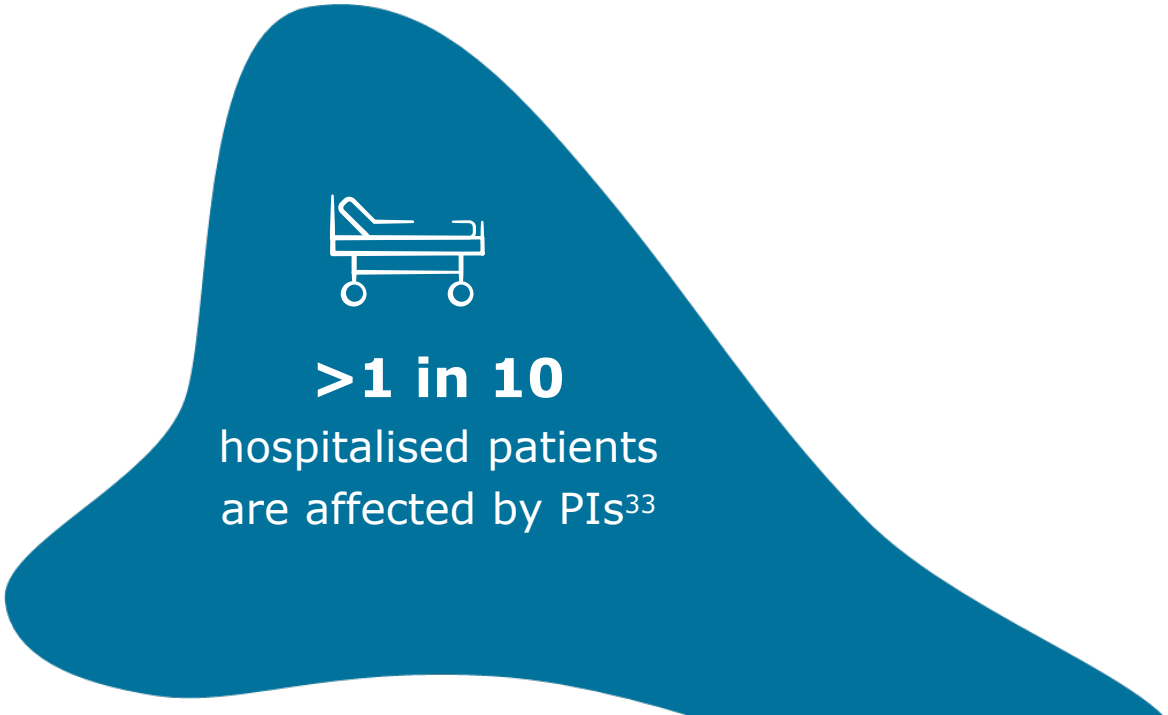
*Calculation for each study based on: 50% reduction in visits;[3] 42% reduction in visits for wounds with high dressing change frequency only;[4] 36% reduction in visits[5]

Evidence overview for **PI prevention**

PI incidence is increasing due to our aging population[32]

Most PIs among hospitalised adults are:[33]

- Preventable
- Likely to occur at the sacrum, heels and hips



When used in addition to standard preventive care, compared with standard preventive care alone in ICU patients:

71%
reduction in sacral PI incidence with ALLEVYN◇ LIFE Dressing[19]

No differences
in effectiveness with ALLEVYN LIFE Dressing and Mepilex™ Border Dressing[21]*

Reductions in sacral PIs with ALLEVYN GENTLE BORDER Dressing[24,25]

*Exploratory analyses; patients treated on ICU (12%) and non-ICU (88%) hospital wards

Evidence overview for **costs** in PI prevention studies

PIs represent a large financial healthcare burden[31,32]

1–5%
Estimated proportion of total healthcare expenditure used for PU treatment in Europe[31,34,35]

$21,767
additional cost of developing a HAPI in the USA[36]

With use of ALLEVYN◇ LIFE Foam Dressing in one study that evaluated costs of PI prevention:[20]

Costs were reduced by 36–69%
estimated cost savings compared with other dressings or standard preventive care[20] (one study)

Chronic wounds
Burden to healthcare systems

In a study of wound care costs in the UK NHS:[28]

District/community nurse visits accounted for 29% of all wound care costs[28]

399%
5-year increase in the number of district/community nurse visits (from 10.9 million to 54.4 million) for acute and chronic wounds[28]

£8.3 billion
annual cost of wound management (2017/18)[28]

More wounds were managed in the community
by GPs, practice nurses, district/community nurses and healthcare assistants than in secondary care[28]

81%
of the total annual NHS cost was incurred in the community[28]

Chronic wounds
Burden to patients

1.5 to 2 million people estimated to be living with a chronic wound across Europe[27]

Chronic wounds can cause **discomfort, pain, malodour, leakage** and **restriction of daily activities**[29,30]

Anxiety, depression and **social isolation** are associated with delayed wound healing[30]

Treatment strategies need to be optimised to effectively manage wounds, and improve patient quality of life[29,30]

Pressure injury prevention
Burden to patients and healthcare systems

The incidence of PIs is increasing due to our aging population[32]

>1 in 10
hospitalised patients are affected by PIs[33]

The majority of PIs among hospitalised adults were:[33]

- Classified as Stage I/Stage II
- **Preventable**
- Most likely to occur at the sacrum, heels and hips

PIs can have a **substantial negative impact on patients** as well as representing a **large financial healthcare burden**[32,34,35]

Mean total treatment costs are **highest for Stage 3 and Stage 4** HAPIs in the USA ($54,151 and $67,198, respectively)[36]

Use of ALLEVYN◇ Foam Dressing in wound management

Tiscar-González V, *et al*. 2021[1]

Study overview

An ambispective (retrospective and prospective) multicentre observational study conducted in Spain between November 2017 and March 2019 at 30 community centres

94 patients
requiring occlusive dressings with expected follow-up of ≥3 weeks

128 wounds
including leg ulcers (39.8%) and PUs (31.3%); 25% of all wounds were >12 months in duration

42%
of previous dressings
were foams (and 21% were gelling fibres)

4 weeks
follow-up after switching to ALLEVYN LIFE Dressing from previous dressings

ALLEVYN LIFE Dressing was used as either a primary (35.2%) or secondary (64.8%) dressing for 4 weeks instead of the previous dressing

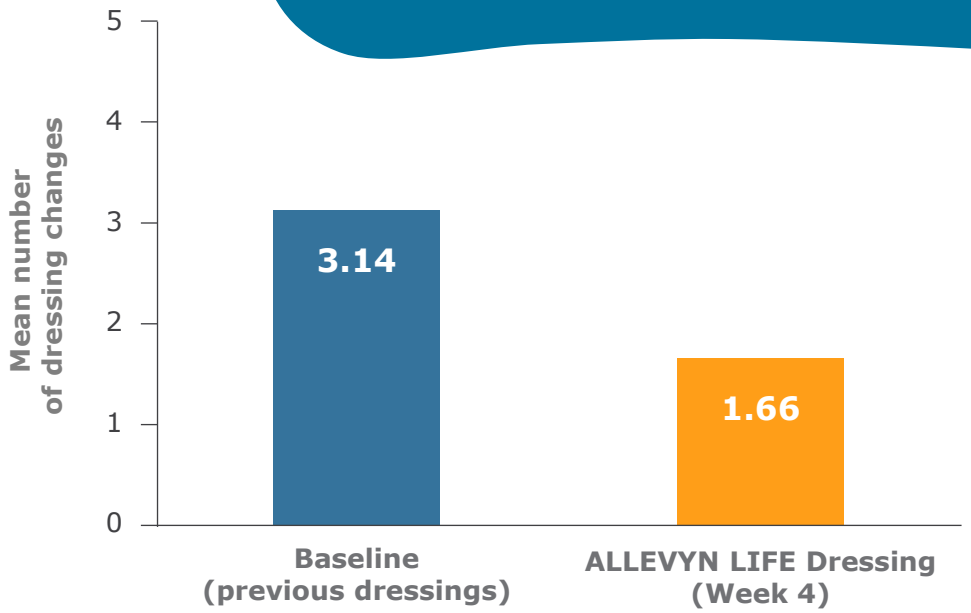
Tiscar-González V, *et al*. 2021[1]

Dressing change frequency and clinician satisfaction

1.48

fewer dressing changes per patient per week

47.1% relative reduction; p<0.001

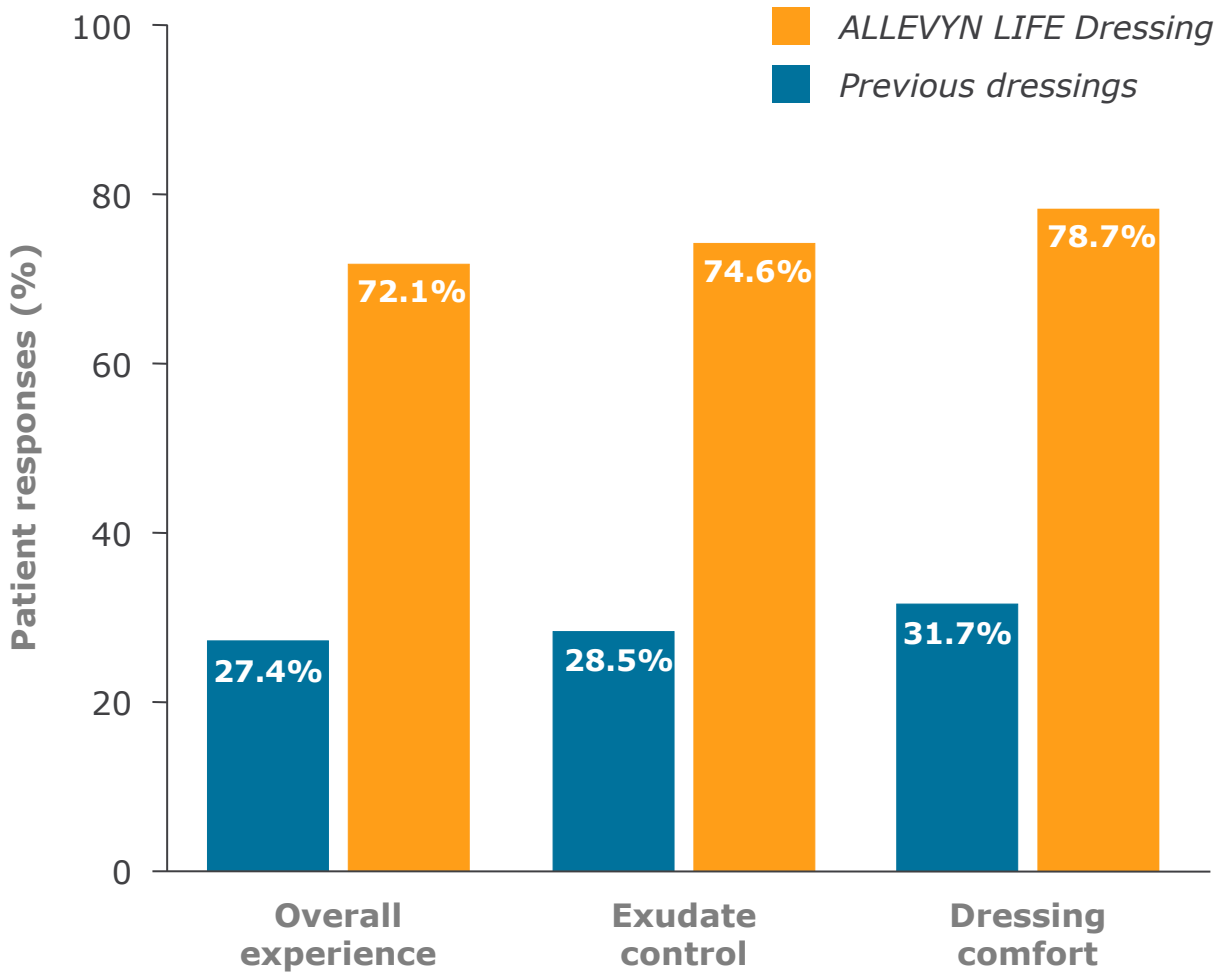


In 92.2% of cases

(118 of 128) HCPs said they would recommend ALLEVYN LIFE Dressing within their healthcare organisation

Tiscar-González V, *et al*. 2021[1]

Patient satisfaction



Most patients (>72%) rated ALLEVYN LIFE Dressing as 'good' or 'very good'
compared with their previous dressings

Tiscar-González V, *et al*. 2021[1]

Mean weekly dressing costs

Cost analysis (weekly, per patient)	Previous dressings	ALLEVYN LIFE Dressing*	
Mean dressing cost	**€27.70** (±94.60)	**€11.45** (±10.23)	**p<0.001**
Mean dressing cost + mean nursing time cost†	**€108.82** (±123.70)	**€55.78** (±33.67)	**p<0.01**

*Mean±standard deviation; †Estimated mean cost of each nurse visit was €27.79

Even at its lowest and highest prices, use of ALLEVYN LIFE Dressing **significantly reduced mean weekly dressing costs per patient** versus previous dressings (p<0.05)

58.6%
relative reduction in mean weekly dressing costs
(€16.25 saving; p<0.001)

Tiscar-González V, *et al*. 2021[1]

Conclusion

Use of ALLEVYN LIFE Dressing in a community setting helped to **significantly reduce the frequency of dressing changes** and **dressing costs** ($p<0.001$) compared with previous dressings, as well as **improve HCP and patient satisfaction**

Krönert GT, *et al*. 2016[2]

Study overview and dressing change frequency

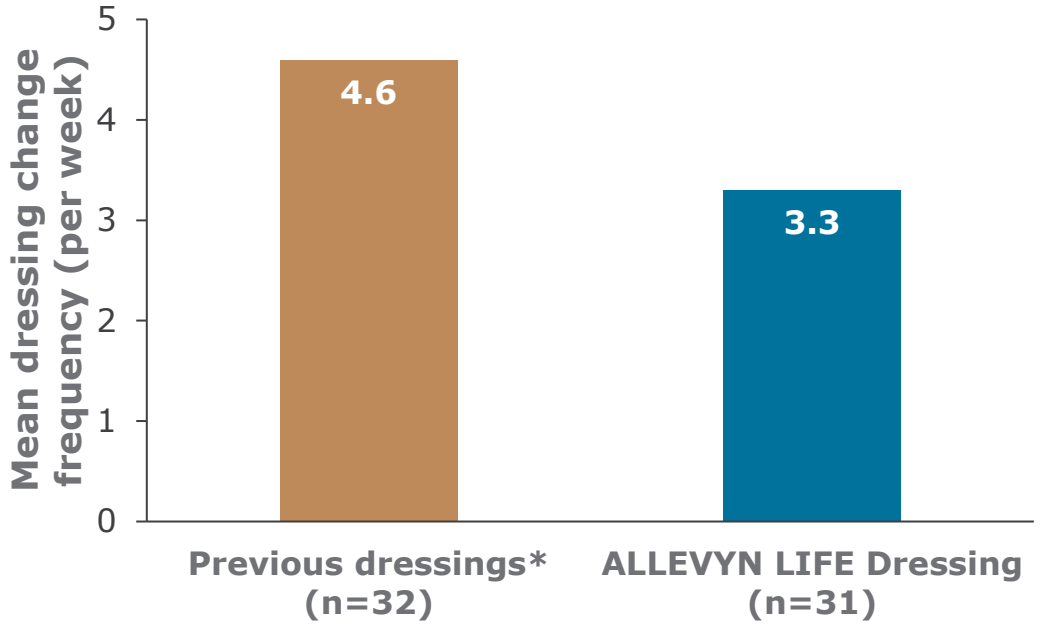
- An audit of resources used over 4 months by two community wound care providers in Germany was conducted following introduction of ALLEVYN◇ LIFE Dressing
- 35 patients were included; most were aged >60 years (74.3%)
- The most common wounds were DFUs (20.0%), VLUs (31.4%) and PUs (28.6%); >75% of wounds were <10cm^2

Use of ALLEVYN LIFE Dressing:

- Increased mean dressing wear time by **0.46 days** (n=31)
- Simplified and rationalised possible dressing combinations (from nine to four)

28%

relative reduction
in mean dressing change frequency
(1.3 fewer per week; n=31)



*Mostly foams

Krönert GT, *et al*. 2016[2]

Costs and user satisfaction

Clinicians rated
ALLEVYN LIFE Dressing
as better than previous dressings
(35 wounds) for:

96.8%
'Overall performance'
and **'Ease of use'**
(30 of 31 responses)

90.3%
'Adhesion'
and **'Wear time'**
(28 of 31 responses)

93.1%
of clinicians
would recommend
ALLEVYN LIFE Dressing
(27 of 29 responses)

Compared with previous dressings clinicians reported decreases in:

- **Wound size** (81.3%; n=32)
- **Exudate level** (75.0%; n=32)
- **Odour** (67.7%; n=31)

22.6% relative reduction
in mean weekly dressing costs
per wound compared with previous dressing
(from €45.81 to €35.46)

Krönert GT, *et al*. 2016[2]

Conclusion

Introduction of ALLEVYN LIFE Dressing in a community wound care setting helped to **reduce mean dressing change frequency and dressing costs** compared with previous dressings; most **clinicians rated it better than previous dressings** and would recommend its use

Joy H, *et al*. 2015[3]

Study overview, dressing changes, costs and nurse visits

- A targeted training programme on wound care practice, including use of ALLEVYN LIFE Dressing, was conducted at a healthcare partnership in the UK
- 37 patients were treated mostly within residential care (40.5%) or at home (43.2%)
- 73.0% of patients had chronic wounds (>6 weeks in duration)

Compared with previous dressings:*

79.6%

reduction in mean number of dressings per patient per week (9.8 to 2.0 dressings)

1,274 visits

(658 hours) estimated to be released per week in a local healthcare practice of 708 patients

64.4%

reduction in **dressing cost per patient per week** (from £28.46 to £10.12)

*Previous dressings included: foam dressings, gelling fibres, hydrocolloids and superabsorbers

Joy H, *et al*. 2015[3]
Dressing change frequency

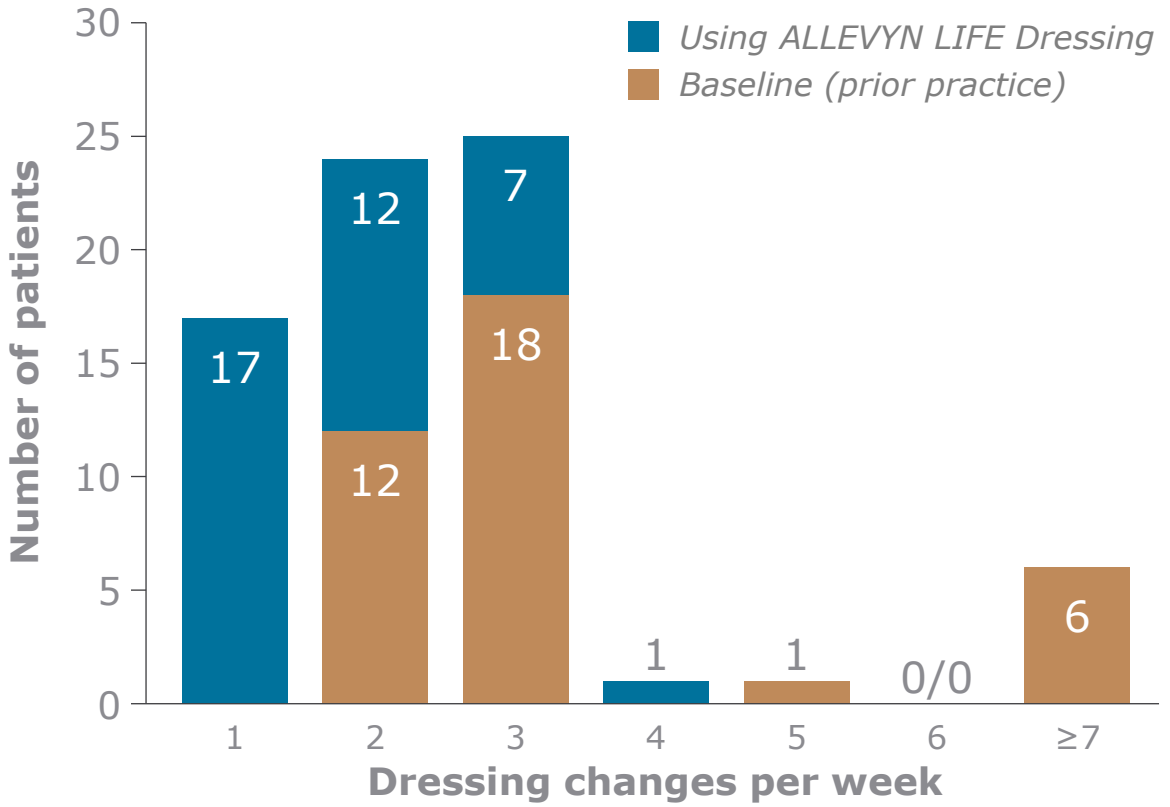
2.3 days

Increased mean dressing wear time (from 2.5 to 4.8 days)

50%

Decreased frequency of dressing change visits per week (from 3.6 to 1.8)

97.3%
of patients (n=37)
had fewer dressing change visits
compared with prior practice



Fewer patients required dressing changes ≥3 times per week after switching to ALLEVYN LIFE Dressing

Joy H, *et al*. 2015[3]

Conclusion

Use of ALLEVYN LIFE Dressing, with a training and education programme, helped to **reduce dressing change frequency, weekly dressing costs per patient and nurse visits** compared with prior practice, and was estimated to result in a **substantial release of valuable nurse time**

Simon D, *et al*. 2014[4]

Study overview, dressing changes, nurse time and costs

- A 4-week, in-practice case series appraisal of switching to ALLEVYN LIFE Dressing from previous dressings* at one NHS Trust in the UK
- Type of wound was recorded for 105 of 109 wounds; the most common were PUs (27.6%) and trauma wounds (22.9%)

~85 hours

of nursing time estimated to be released per week

(166 visits per week)†

£5,950

of estimated savings per week†

42.6%

decrease in mean weekly dressing change frequency

(from 4.7 to 2.7; where dressings were previously changed ≥3 times per week, n=28)

*Mostly other foams

†Across 83 wounds requiring ≥3 dressing changes per week

Simon D, *et al*. 2014[4]

Dressing wear time and clinician satisfaction

48.7%
increase in mean
wear time of dressing
(from 3.5 to 5.2 days; n=97)

98%
of nurses
would recommend
ALLEVYN LIFE Dressing*

90%
of nurses rated
ALLEVYN LIFE Dressing
as 'good' to 'excellent'*

*Based on either n=103 or n=105 survey responses

Simon D, *et al*. 2014[4]

Conclusion

Switching to ALLEVYN LIFE Dressing helped to **increase mean wear time and reduce mean dressing change frequency** compared with previous dressings, which may improve practice efficiency. ALLEVYN LIFE Dressing was **rated highly by community nurses**, most of whom **recommended its use in their practice**

Stephen-Haynes J, *et al*. 2013[5]

Study overview, wear time, dressing changes and nurse visits

- An in-practice clinical performance appraisal of switching to ALLEVYN LIFE Dressing from previous dressings* at one UK NHS Trust
- 38 nurses were trained on the protocol and 40 cases were completed
  - Most were from primary care (79.5%)
  - PUs (40.0%) and trauma wounds (24.3%) were the most common wounds

36.3%
reduction in mean weekly **dressing change frequency** (from 4.52 to 2.88; n=28)†

67.9% ↑
increase in mean **wear time** (from 2.15 to 3.61 days; n=28)†

397 estimated hours released per week (769 visits)
when reductions in dressing change frequency are applied to a local healthcare practice of 469 patients requiring ≥3 visits per week

*Previous dressings included: film dressings, foam dressings and non-woven dressings
†Calculated for 28 cases that had data for both ALLEVYN LIFE Dressing and the previous dressing

Stephen-Haynes J, *et al*. 2013[5]

High clinician satisfaction

94%

of nurses (n=38)
would recommend inclusion
of ALLEVYN LIFE Dressing
on wound care formulary

>90%

of nurses (n=38)
rated ALLEVYN LIFE Dressing
as 'good' to 'excellent'
(across 13 performance parameters)

Stephen-Haynes J, *et al*. 2013[5]

Conclusion

Switching to ALLEVYN LIFE Dressing helped to **reduce dressing change frequency** and **increase mean wear time**, and was **rated highly by nurses** compared with previous dressings; it may also **enhance efficiency** by releasing nursing visits

Rossington A, *et al*. 2013[6]
Study overview and clinician satisfaction

- A prospective, non-comparative evaluation of ALLEVYN LIFE Dressing in patients (n=148) with a range of wound types (one wound per patient was evaluated)
- Patients received a maximum of four dressing changes or up to 14 days of treatment in a variety of care settings
- Clinicians completed a questionnaire at baseline, dressing change and discontinuation

86%
of clinicians
were satisfied with all performance parameters

Clinicians were most satisfied with:

98%
Ease of application and removal

91%
Conformability

>50%
rated ALLEVYN LIFE Dressing better than the usual dressing*
across all performance parameters

*Mostly other foams

Rossington A, *et al*. 2013[6]

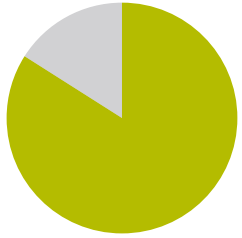
Patient satisfaction

83%
of patients (n=148)
were satisfied with use
of ALLEVYN LIFE Dressing

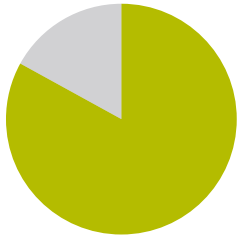
45%
of patients (n=148)
said the dressing had a positive
effect on living with a wound

No pain at dressing removal
in 83% of assessments (n=148)

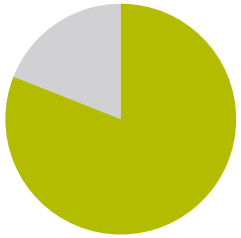
The highest numbers of satisfied patients (n=148) were recorded for:



84%
Comfort during wear



83%
Wound protection



81%
Pain on removal

Rossington A, *et al*. 2013[6]

Conclusion

Clinician and patient satisfaction with ALLEVYN LIFE Dressing was high, which may have a positive impact on wound healing and patient wellbeing

Callaghan R, *et al*. 2012[7]
Study overview

Case series evaluation on the use of ALLEVYN GENTLE BORDER Multisite Foam Dressing

- 10 patients with a variety of chronic wounds

Clinicians evaluated several parameters including dressing features:

- Fitting awkward areas
- Ease of application/removal
- Patient comfort during wear time/removal
- Ability to handle exudate/stay in place
- Changes in patient quality of life

For each of these categories, the clinician was asked to rate the dressing as ‘poor’, ’fair,’ ’good’, ’very good’ or ‘excellent’

Callaghan R, *et al*. 2012[7]

Patient-centred care and wellbeing

In patients with a range of chronic wounds,
ALLEVYN GENTLE BORDER Multisite Dressing:

Effectively managed wounds in **awkward anatomical areas**

Was rated by most clinicians as **'very good' or 'excellent'** at first and last dressing change across the key performance criteria

Patient **quality of life** improved during treatment versus previous dressings

Callaghan R, *et al*. 2012[7]

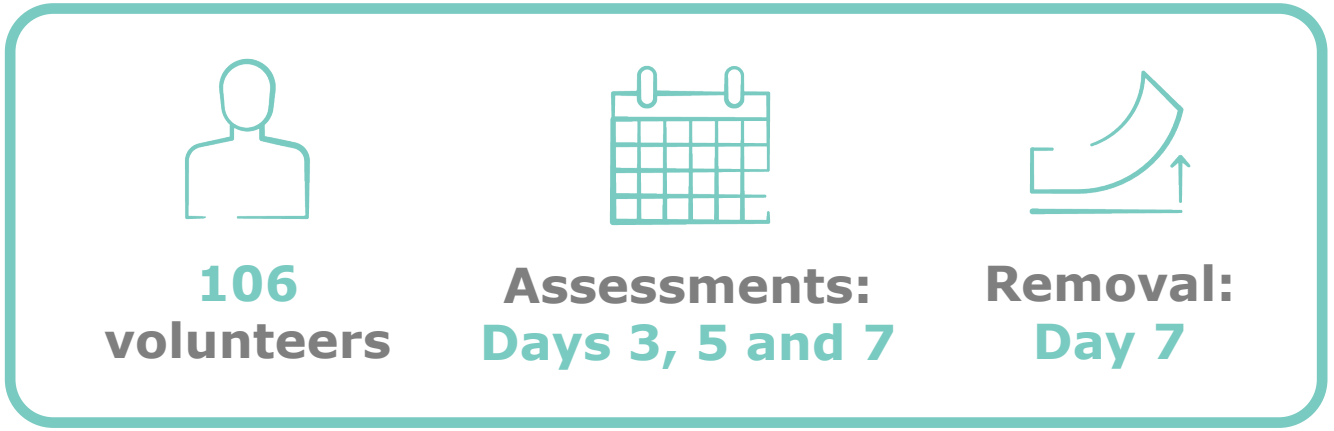
Conclusion

ALLEVYN GENTLE BORDER Multisite Dressing improved patient quality of life and could be used on complex wounds in **awkward anatomical areas,** with the clinicians rating the dressing as '**very good**' or '**excellent**' in the majority of key performance criteria

Palmer S, *et al*. 2012[8]

Study overview

- Open label, prospective, randomised, comparative, volunteer study
- Compared the performance of ALLEVYN GENTLE BORDER Multisite Dressing* with Mepilex™ Border dressing (Mölnlycke, Sweden)
- 106 volunteers (mean age: 40 years) randomised to ALLEVYN GENTLE BORDER Multisite Dressing or Mepilex™ Border dressing applied to one of their elbows or knees



*Previously known as the HYDROCELLULAR◇ Silicone Gel Adhesive Foam Dressing

Palmer S, *et al.* 2012[8]

Retention, conformability and clinical acceptability

ALLEVYN GENTLE BORDER Multisite Dressing was significantly ($p \leq 0.05$) better versus Mepilex™ Border dressing for:

- Retention on the elbows at 7 days (11.5% difference)
- Retention on the knees at 5 days (12.6% difference) and 7 days (11.7% difference)
- Conformability on the elbows at 5 days (35.1% difference) and 7 days (29.6% difference)
- Conformability on knees at 3 days (20.8% difference) and 5 days (22.2% difference)

Greater clinical acceptability*
with ALLEVYN GENTLE BORDER Multisite Dressing versus Mepilex™ Border dressing
($p \leq 0.05$; all time points)

*Absence of dressing lift compromising the protective barrier function of the dressing

Palmer S, *et al.* 2012[8]

Conclusion

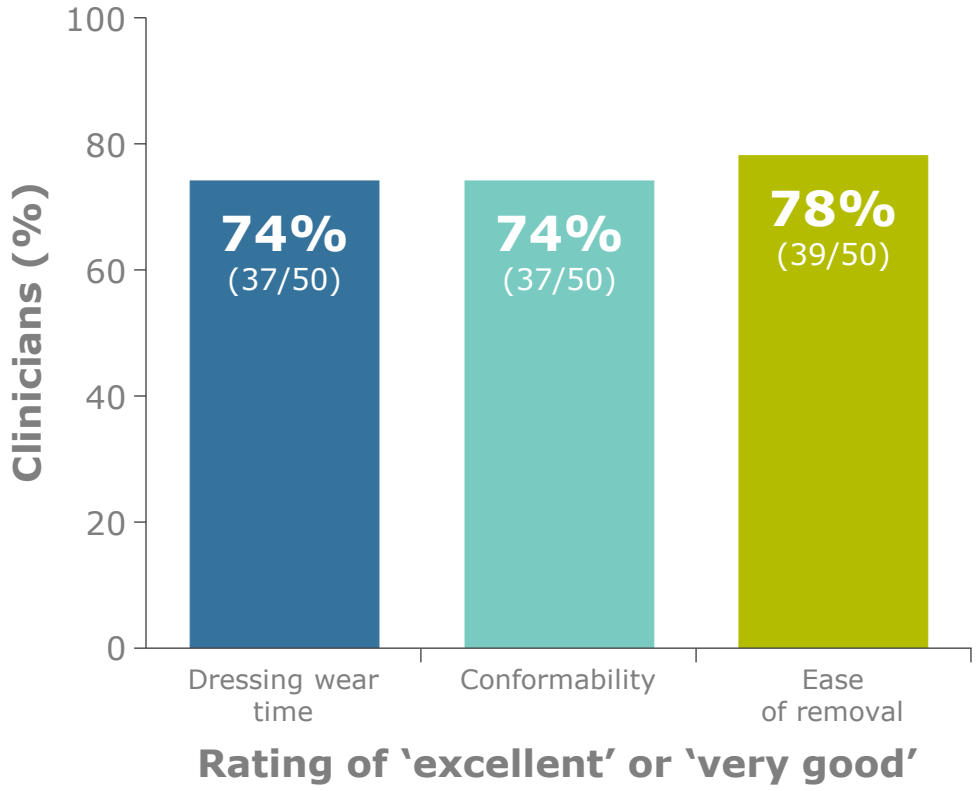
ALLEVYN GENTLE BORDER Multisite Dressing **exhibited superior performance** to Mepilex™ Border dressing in terms of number of dressings in place on the knees (Days 5 and 7) and on the elbows (Day 7) in volunteers

Stephen-Haynes J, *et al.* 2011[9]

Wear time, conformability and ease of removal

A clinical evaluation of ALLEVYN GENTLE BORDER LITE Foam Dressing in patients with acute and chronic wounds (N=50)

- 44% had fragile skin at baseline



Stephen-Haynes J, *et al.* 2011[9]

Conclusion

ALLEVYN GENTLE BORDER LITE Dressing allowed for a **secure fit,** could be applied to patients with fragile skin, and could be used on difficult-to-dress areas

Hampton S. 2010[10]

Study overview

- Evaluation of ALLEVYN GENTLE BORDER Heel Foam Dressing in 20 patients (mean age: 78.4 years)
- Decision to use ALLEVYN GENTLE BORDER Heel Dressing was made before inclusion in the study
- Wounds suited to the product indications:
  - 80% PUs
  - 5% DFUs
  - 15% other

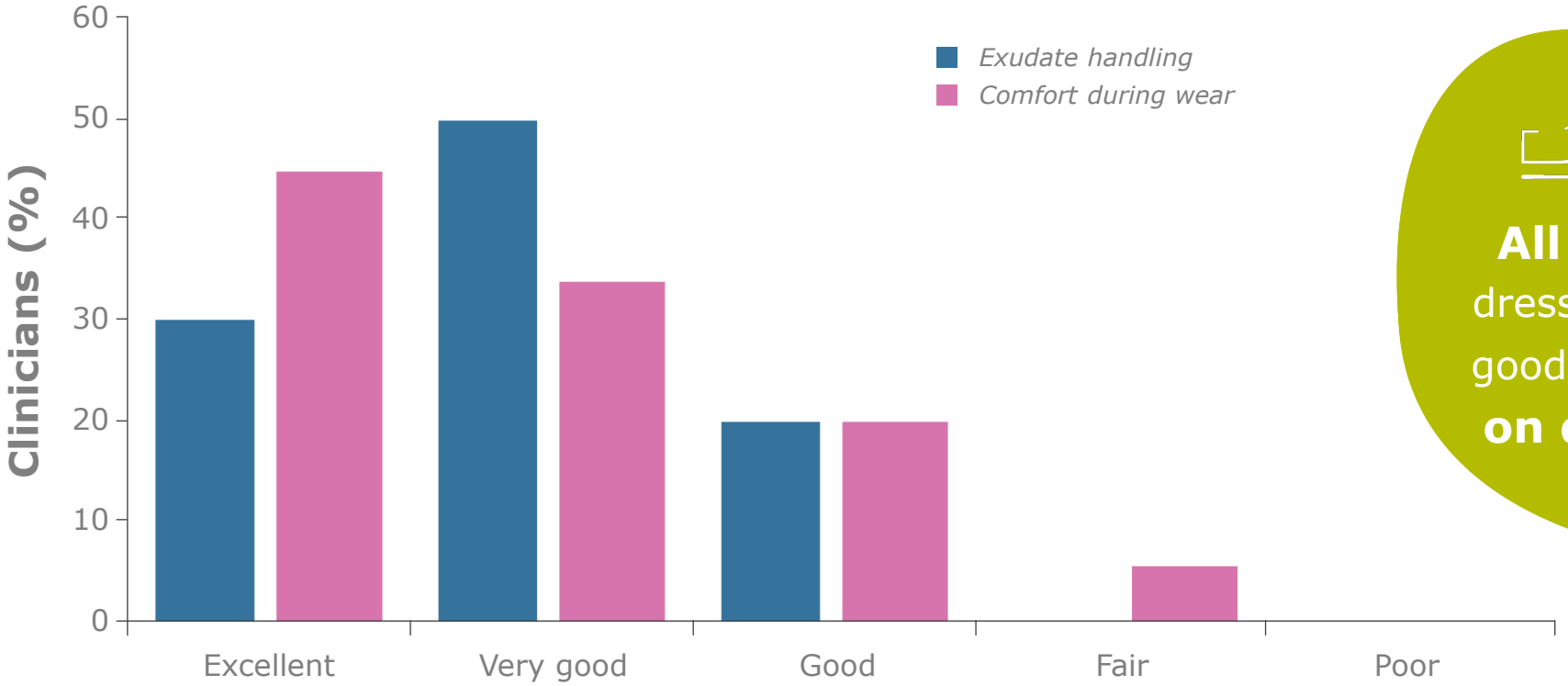
Mean wound area was 13.1cm²

- 8% light or no exudate
- 55% moderate exudate
- 5% heavy exudate

41.4 days mean wound duration

Hampton S. 2010[10]
Exudate management and patient comfort

- 70% of patients (14/20) had healthy periwound skin at study end (vs 25% at baseline)
- Direct link between the amount of exudate retained in the dressing, patient comfort, and ability of the dressing to retain position on the skin



All patients rated the dressing as excellent, very good or good for **comfort on dressing removal**

Hampton S. 2010[10]

Conclusion

ALLEVYN GENTLE BORDER Heel Dressing was **comfortable** for patients, **managed exudate effectively** and **stayed in place** in patients with heel wounds

Hurd T, *et al*. 2009[11]

Study overview

A multicentre clinical evaluation that examined the performance and clinical acceptability of ALLEVYN GENTLE BORDER Foam Dressing in the management of a range of wounds in a variety of clinical settings

- Acute and chronic wounds were treated, including PUs, VLUs, DFUs, burns, donor sites, fungating/malignant wounds and surgically dehisced wounds

153
adult patients recruited across six countries

45%
of patients completed 4–6 dressing changes during the study
(69/153 patients)

33%
of wounds had healed before the end of the study period
(51/153 patients)

Hurd T, *et al*. 2009[11]
Clinical acceptability

When compared with baseline (prior dressings), the use of ALLEVYN GENTLE BORDER Dressing resulted in:

Reduction in exudate levels
by final assessment
(from 99% to 56%, p<0.001)

63%
median reduction
in wound depth
(from 0.2 to 0cm; p<0.001)

69%
median reduction
in wound area
(from 3.8 to 0.8cm^2; p<0.001)

3.6 days
mean recorded wear time
(n=111, range: 0.6–7.0 days)

Hurd T, *et al*. 2009[11]

Costs and satisfaction

Mean cost per week
of ALLEVYN GENTLE BORDER Dressing was **£7.69** per patient
(versus £8.18 for other dressings and products)

No pain on removal
reported at **93%** of dressing changes (542/583)

95%
of clinicians (145/152) found ALLEVYN GENTLE BORDER Dressing to be **acceptable for the wound type** treated

Hurd T, *et al*. 2009[11]

Conclusion

ALLEVYN GENTLE BORDER Dressing
was **effective in improving wound outcomes**
in conjunction with routine clinical practice,
resulting in cost savings

Grothier L. 2009[12]

Study overview

An international multicentre clinical in-market evaluation of the ALLEVYN GENTLE range of dressings (interim data)

ALLEVYN GENTLE Dressing
evaluated in 37 patients

Most were leg ulcers (48.6%), trauma wounds (16.2%) or DFUs (16.2%)

ALLEVYN GENTLE BORDER Dressing
evaluated in 30 patients

Most were traumatic (26.7%) and surgical (33.3%) wounds

Grothier L. 2009[12]
Interim results

Dressing changes were less time consuming than prior practice and did not need to be undertaken by HCPs

ALLEVYN GENTLE Dressing
acceptance rate for use
in the indication treated

97%

ALLEVYN GENTLE BORDER Dressing
acceptance rate for use
in the indication treated

87%

ALLEVYN GENTLE Dressing
- **97%** exudate handling satisfaction
- **88%** no pain during removal
- **≥98%** for comfort during wear, for ease of application and for ease of removal

ALLEVYN GENTLE BORDER Dressing
- **86%** exudate handling satisfaction
- **96%** no pain during removal
- **≥98%** for comfort during wear, for ease of application and for ease of removal

Grothier L. 2009[12]

Conclusion

ALLEVYN GENTLE Dressing
and ALLEVYN GENTLE BORDER Dressing
were **positively rated** by both clinicians
and patients in terms of **performance,**
comfort and dressing removal

Leak K, *et al*. 2010[13]
Study overview

- Multicentre clinical evaluation to assess performance of ALLEVYN GENTLE Dressing
- Adults (N=56) from Germany, Ireland, Netherlands, Spain and the UK were included
- Median baseline reference wound area was 7.6cm^2 and median depth was 0.3cm

52%
(29/56 patients)
completed
4–6 dressing changes

17 days
median study duration
(range, 0 to 53 days)

VLUs
were the most
common wound type
(18/56, 32%)

Leak K, *et al*. 2010[13]
Clinical acceptability and cost outcomes

From baseline (prior dressing) to final assessment there was a **significant reduction** in wound area, wound depth and level of exudate with use of ALLEVYN GENTLE Dressing (all p<0.001)

- 21% of wounds healed

87%
of patients reported **no pain** at dressing removal

95%
clinical acceptability

3.3 days
mean patient **wear time***

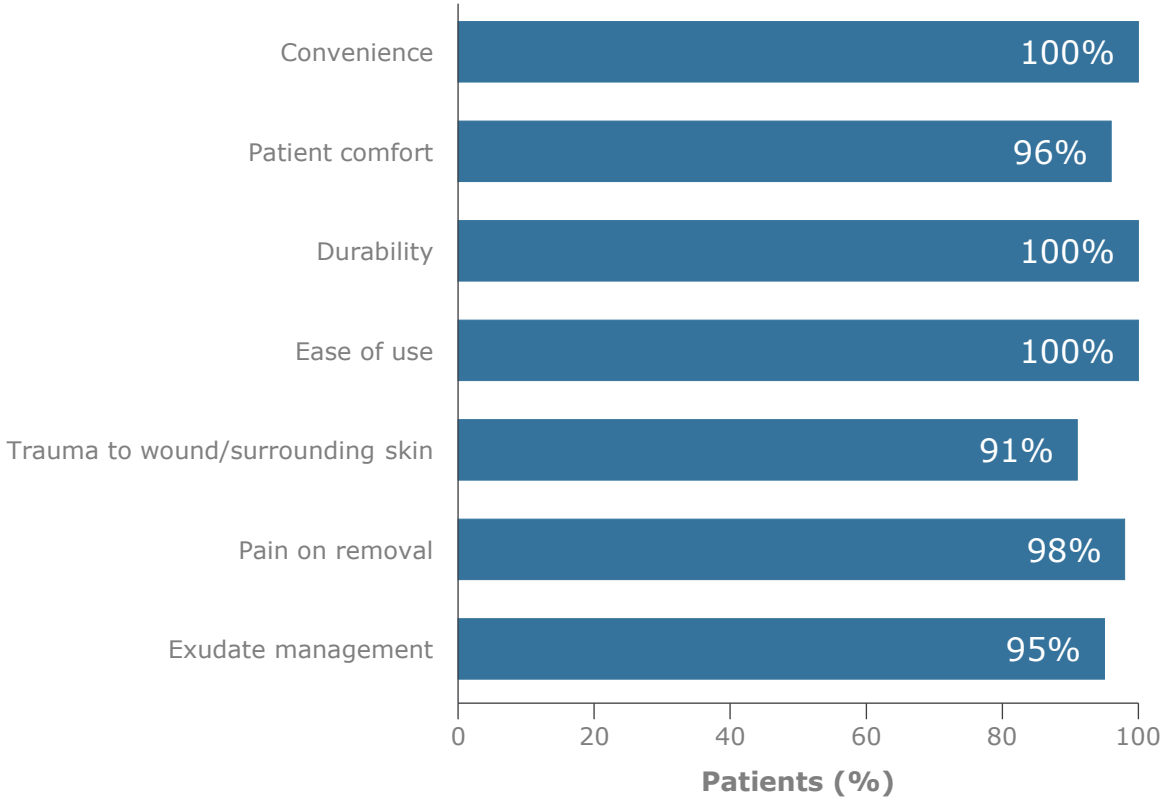
80%
of assessments: dressing was **fully adhered before removal**

£2.90
estimated saving
per patient per week

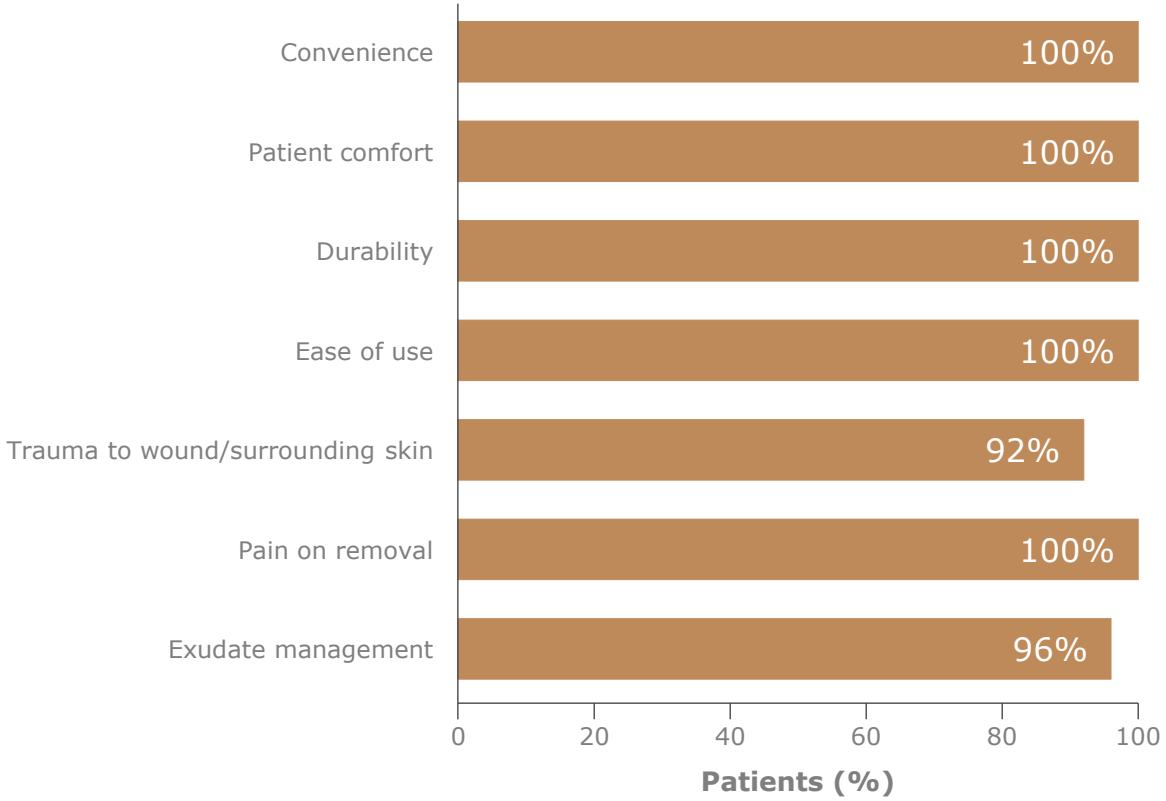
*Derived from duration between assessments and number of dressing changes between assessments

Leak K, *et al*. 2010[13]
Product performance characteristics

Satisfaction with ALLEVYN GENTLE Dressing **met or exceeded expectations** for most patients (n=55)



ALLEVYN GENTLE Dressing **performance** was the **same or better** for patients who had used other silicone dressings (n=25)



Leak K, *et al*. 2010[13]

Conclusion

ALLEVYN GENTLE Dressing
was acceptable to clinicians and patients
with **reduced dressing costs**

Chamorro A, *et al*. 2019[14]
Study overview

Comparative multicentre study of ALLEVYN ADHESIVE Dressing (n=84) and Varihesive™ Gel Control dressing (Factormed, Portugal; n=85)

Patients with Category 2 PUs received either study dressing plus standard preventive care

- 169 patients (mean age: 81.3 years) at 29 primary and 10 long-term care centres in Spain
- Baseline risk for PUs:
  - 30% had a high risk
  - 21% had a moderate risk
  - 33% had a low risk
  - 16% had no risk

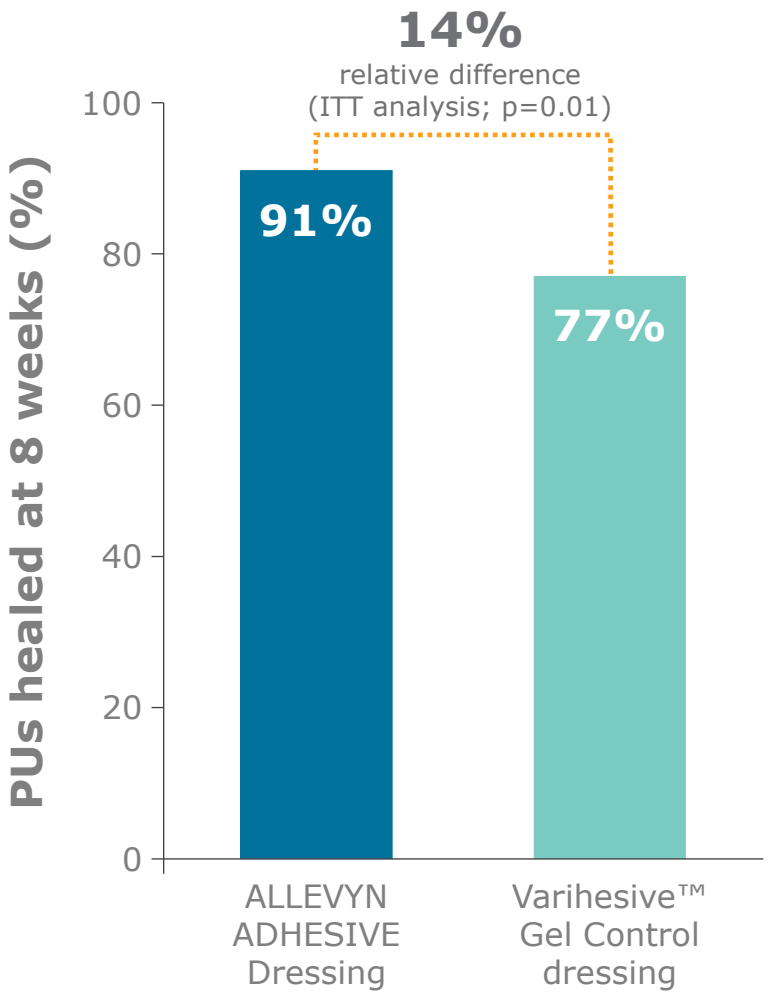
Primary outcome:
healing of the Category 2 PU within 8 weeks

Secondary outcomes:*
- Direct costs
- Usability assessment
- Dressing safety

*5–10% of patients (random selection) were monitored for secondary outcomes

Chamorro A, *et al*. 2019[14]

Clinical outcomes, cost and satisfaction



Patients and caregivers rated ALLEVYN ADHESIVE Dressing **as significantly better** in terms of **comfort** (p=0.011)

Nurses considered it **significantly better** for **ease of removal, absorption, effect on perilesional skin and healing time** (p<0.01)

No difference in cost between groups (€61.80 for ALLEVYN ADHESIVE Dressing vs €60.10 for Varihesive™ Gel Control dressing)

Chamorro A, *et al*. 2019[14]

Conclusion

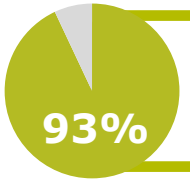
More Category 2 PUs healed within 8 weeks using ALLEVYN ADHESIVE Dressing than Varihesive™ Gel Control dressings and it was rated significantly better by patients for comfort and nurses for ease of removal, absorption, effect on perilesional skin and healing time

Leonard S, *et al*. 2009[15]

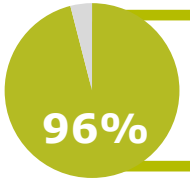
Study overview

An in-market evaluation of the performance of ALLEVYN Wound Dressings in clinical practice:

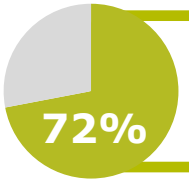
- 27 centres in France, Ireland, Italy, Spain and the UK (public and private hospitals, non-hospital wound clinics, home care services)
- 197 patients with a range of chronic wounds (59 surgical and trauma wounds, 54 PUs, 34 other/unclassified, 29 VLUs, 21 DFUs)
- Evaluated dressings were:
  - ALLEVYN ADHESIVE Dressing (n=84)
  - ALLEVYN NON-ADHESIVE Dressing (n=84)
  - ALLEVYN SACRUM Foam Dressing (n=3)
  - ALLEVYN PLUS ADHESIVE Dressing (n=6)
  - ALLEVYN PLUS ADHESIVE SACRUM Dressing (n=5)
  - Unclassified dressings (n=15)



Dressings classed as satisfactory for absorbency



Absorbency satisfaction for moderate exudate



Absorbency satisfaction for heavy exudate

Clinician satisfaction with absorbency at dressing change was 97% where ALLEVYN Wound Dressings were the primary dressing

Leonard S, *et al*. 2009[15]
Clinical outcomes

With use of ALLEVYN Wound Dressings to help manage chronic wounds:

Reductions
in median **wound area**
and depth were **95%**
and **100%**, respectively
(after a median of 41.5 days)

43%
of wounds healed
during the study

21% of patients
had a reduction
in clinical signs of infection
(from 29% at baseline,
8% at final assessment)

Leonard S, *et al*. 2009[15]

Conclusion

ALLEVYN Wound Dressings
had **high clinician satisfaction ratings**
for key performance criteria when used to
help manage acute and chronic wounds

White R, *et al*. 2007[16]
Study overview

- Clinical in-market evaluation (N=82) conducted across 13 centres in France, Ireland, Italy, Spain and the UK (interim data)
- Enhanced versions of ALLEVYN Wound Dressings were evaluated for wear time, absorbency and exudate management in a range of wound types (including PUs, VLUs and DFUs)
- Initial assessment was followed by repeat assessments at every dressing change for 4–12 weeks

Enhanced versions tested were:

- ALLEVYN ADHESIVE Foam Dressing (n=26)
- ALLEVYN PLUS ADHESIVE Dressing (n=6)
- ALLEVYN PLUS ADHESIVE SACRUM Dressing (n=2)
- ALLEVYN NON-ADHESIVE Dressing (n=43)

4.4 days
mean wear time for all dressings
(range: 3.8 days for 'heavy' exudate to 5.5 days for 'slight' exudate)

White R, *et al*. 2007[16]

Wound healing outcomes and clinician satisfaction

Reduction in devitalised tissue
(mean baseline value of 47.6%
to a mean of 10.6% at final assessment)

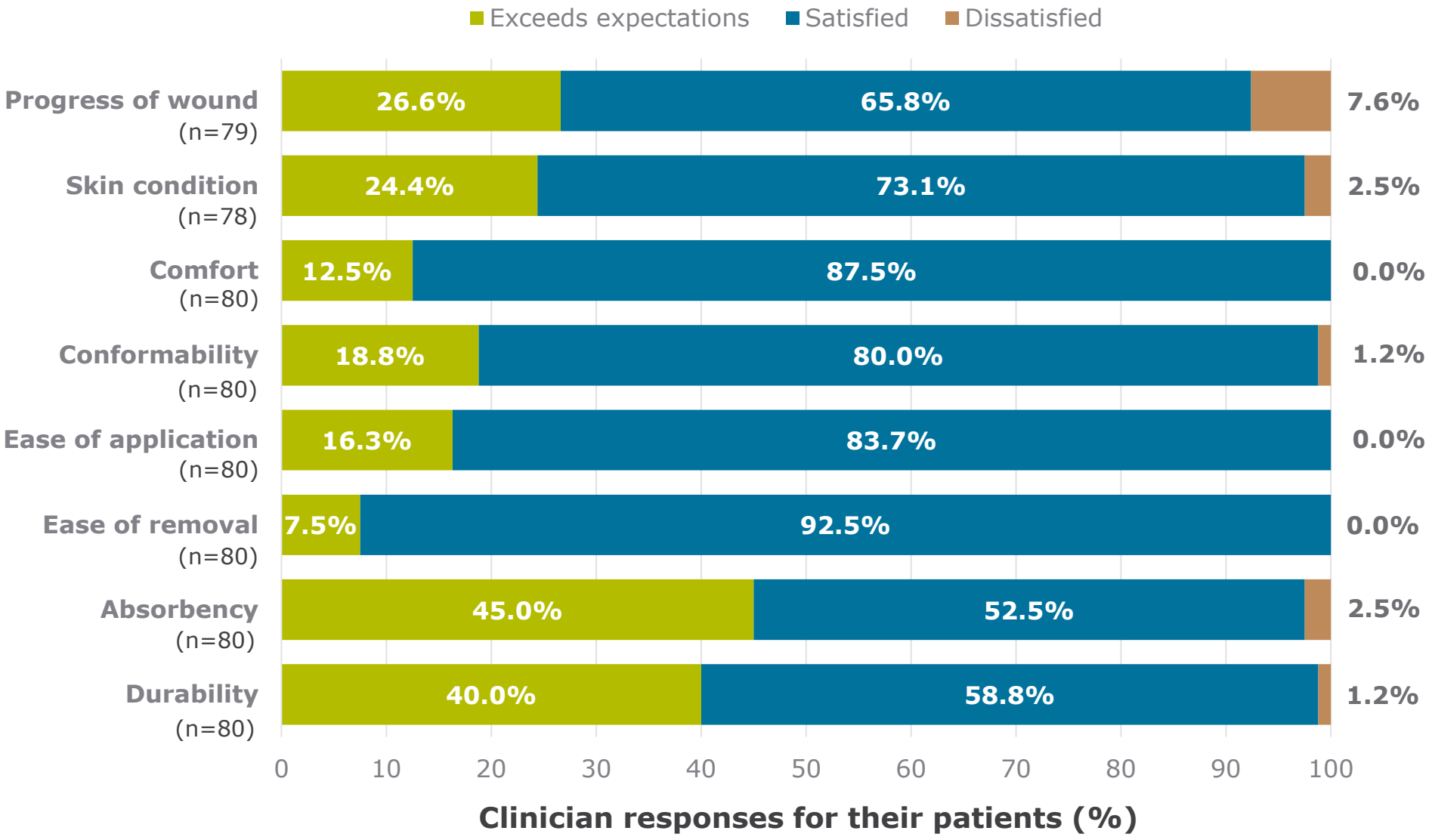
Increase in the proportion
of patients with **healthy skin**
(26.8% to 70.9%)

Dressing application and **removal**
were judged to be **easy** in most instances
(99.2% for dressing application
and 96.7% for dressing removal)

Clinicians regarded
the dressings as **acceptable**
for **96.3%** of patients (77/80)

White R, *et al*. 2007[16]

Clinician assessment of dressing performance



White R, *et al*. 2007[16]

Conclusion

Clinicians rated ALLEVYN Wound Dressings as acceptable for most patients with acute and chronic wounds; they were easy to apply and remove, with high absorbency

Young S. 2007[17]

Study overview

A non-comparative study where users (N=120) were asked to evaluate four ALLEVYN Wound Dressings versus the original dressings

Patients with acute and chronic wounds (low to heavily exuding) rated the enhanced dressings versus their previous experience with the original ALLEVYN Dressings

Dressings evaluated were:

- ALLEVYN ADHESIVE Dressing
- ALLEVYN PLUS ADHESIVE SACRUM Dressing
- ALLEVYN NON-ADHESIVE Dressing
- ALLEVYN GENTLE BORDER LITE Dressing

Dressings had been **enhanced to increase fluid uptake** and **improve the fluid management profile**

Young S. 2007[17]
Dressing performance

Patients (N=120) were asked to rate appearance, conformability, dressing fixation, absorbency and wear time of the enhanced dressings versus the original ALLEVYN Wound Dressings

Patients reported the following improvements:

52% for wear time

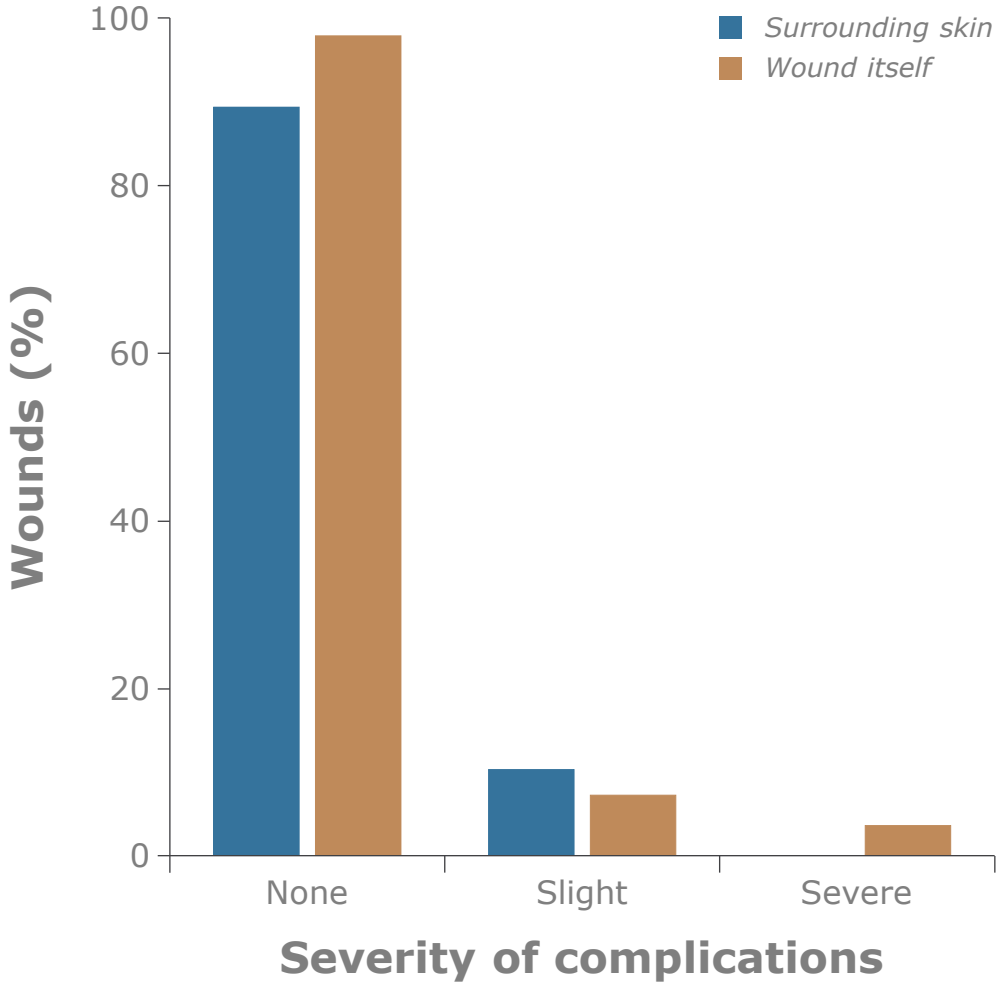
46% for conformability

94% rated the dressings as **acceptable for the wound**

72% of patients rated absorbency as better than the original dressing

Young S. 2007[17]

Wound outcomes



89%

of 120 patients reported no periwound complications at dressing removal

No reports

of **severe complications** during 386 dressing changes

Young S. 2007[17]
Conclusion

Patients reported **improvements in absorbency, wear time and adhesion** versus the original ALLEVYN Dressings, which may lead to a reduction in dressing change frequency

Franks P, *et al*. 2007[18]

Study overview and clinical outcomes

Multicentre, prospective, randomised trial to evaluate ALLEVYN NON-ADHESIVE Dressing and Mepilex™ dressing (Mölnlycke, Sweden) in patients (N=156) with VLUs

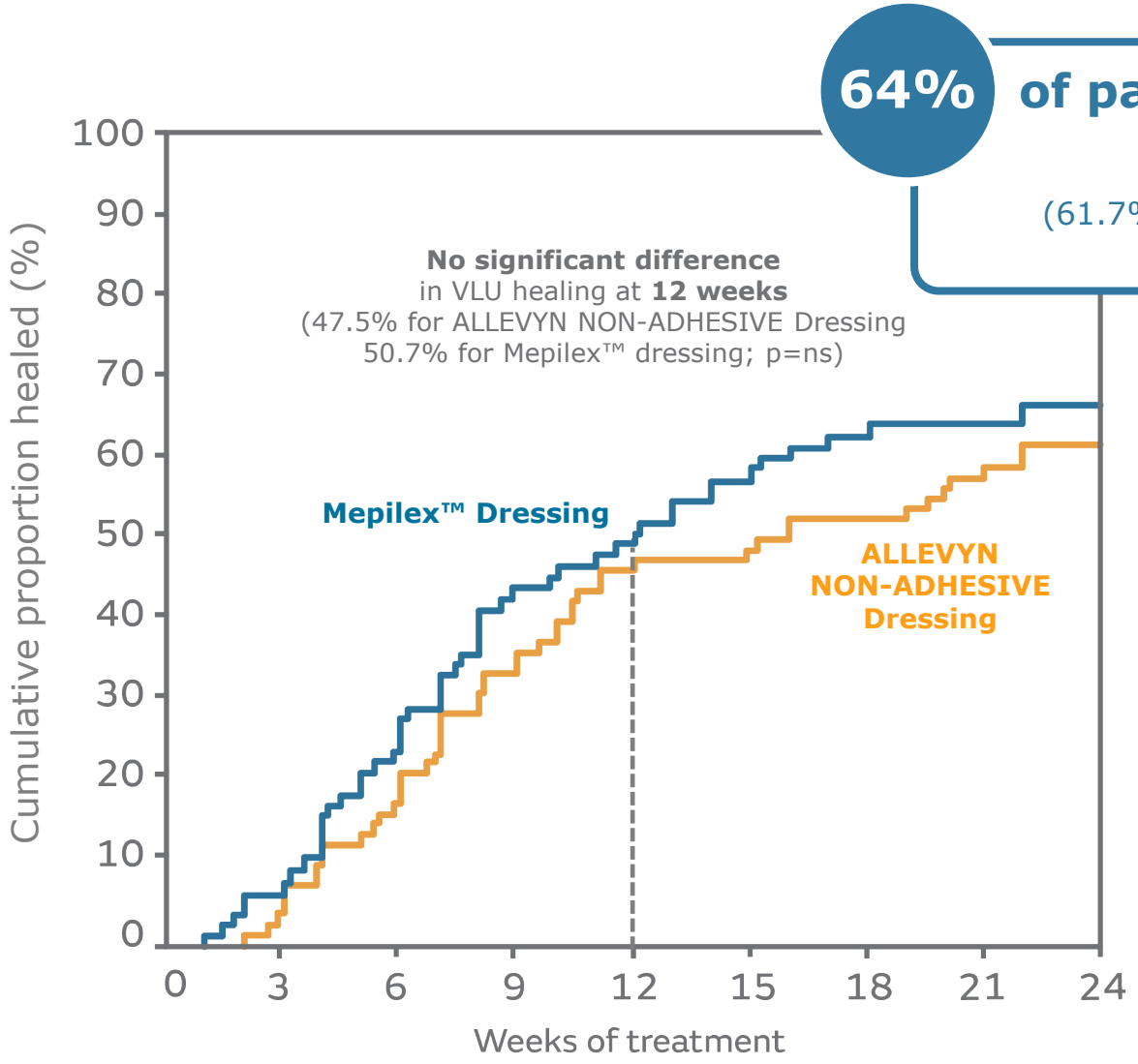
- Patients were randomised to ALLEVYN NON-ADHESIVE Dressing (n=81) or Mepilex™ dressing (n=75), and to one of two bandage systems
- Redressing and rebandaging was undertaken weekly unless required more frequently on clinical grounds
- Trial duration was 24 weeks, or until wound closure
- Median ulcer size at baseline was 4.33cm^2 (0.3 to 123.1cm^2)

64.2%
of VLUs were closed
at 24 weeks

(50 of 81 patients for ALLEVYN NON-ADHESIVE Dressing and 50 of 75 patients for Mepilex™ dressing)

Franks P, *et al*. 2007[18]

VLU closure and pain outcomes



64% **of patients achieved VLU closure at 24 weeks**

(61.7% for ALLEVYN NON-ADHESIVE Dressing and 66.7% for Mepilex™ dressing)

- Changing dressings improved levels of pain
- Over time, pain scores reduced, with 4-week scores significantly lower than at baseline for pre-dressing, post-dressing change, sensory pain and affective pain (all $p<0.001$)
- No significant difference in pain score between the two groups

Franks P, *et al*. 2007[18]

Conclusion

Performance of ALLEVYN NON-ADHESIVE Dressing and Mepilex™ dressing was **similar** in patients with VLUs; wound healing status and pain reductions were also **similar**

Use of ALLEVYN◇ LIFE Foam Dressing and ALLEVYN GENTLE BORDER Dressing in pressure injury prevention

Forni C, *et al*. 2018[19]
Study overview

- Randomised controlled trial to determine whether ALLEVYN LIFE Dressing is effective in reducing the onset of sacral PUs
- Patients with hip fragility fracture who were aged ≥65 years (without a PU in the sacral area) were eligible for inclusion
- ALLEVYN LIFE Dressing plus standard preventive care was compared with standard preventive care alone

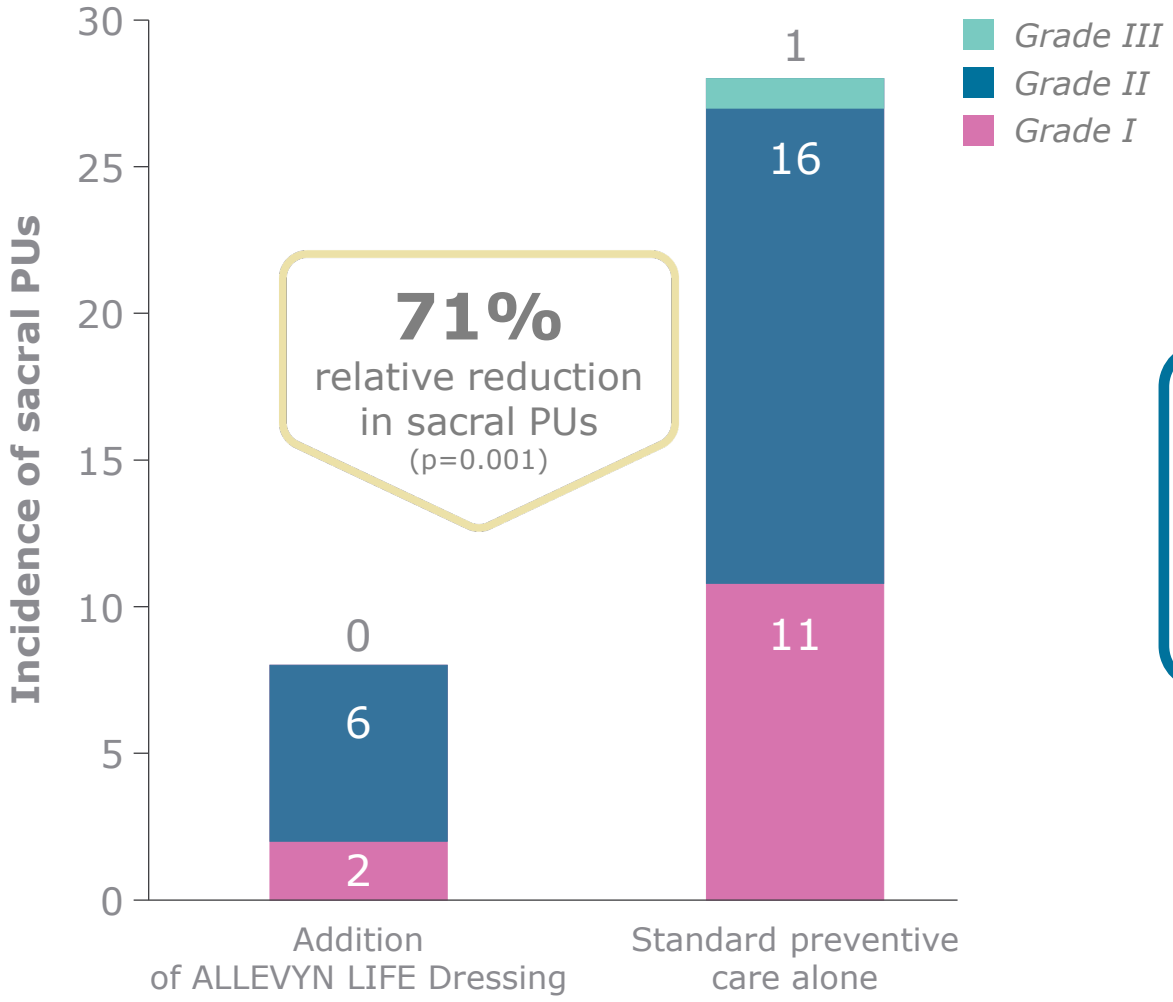
359 patients enrolled

- 177 to ALLEVYN LIFE Dressing plus standard preventive care
- 182 to standard preventive care alone

ALLEVYN LIFE Dressing was applied to the sacrum within 24hrs of hospital admission and replaced when it came unstuck or got wet or dirty

Forni C, *et al*. 2018[19]

Incidence of sacral PUs (all grades)



ALLEVYN LIFE plus standard preventive care **reduced the incidence of all grades of sacral PUs** compared with standard preventive care alone

Forni C, *et al*. 2018[19]
Other key findings

Significantly fewer patients developed a PU with ALLEVYN LIFE Dressing and standard prevention care (n=8) than with standard preventive care alone (n=28; 4.5 vs 15.4%; p=0.001)

Significantly longer time to injury with ALLEVYN LIFE Dressing (Day 6) versus standard preventive care alone (Day 4) (p=0.001)

The dressing was **not rolled back or detached** despite daily inspections

9

Number of dressings needed (number needed to treat) to help prevent one PU

Forni C, *et al*. 2018[19]

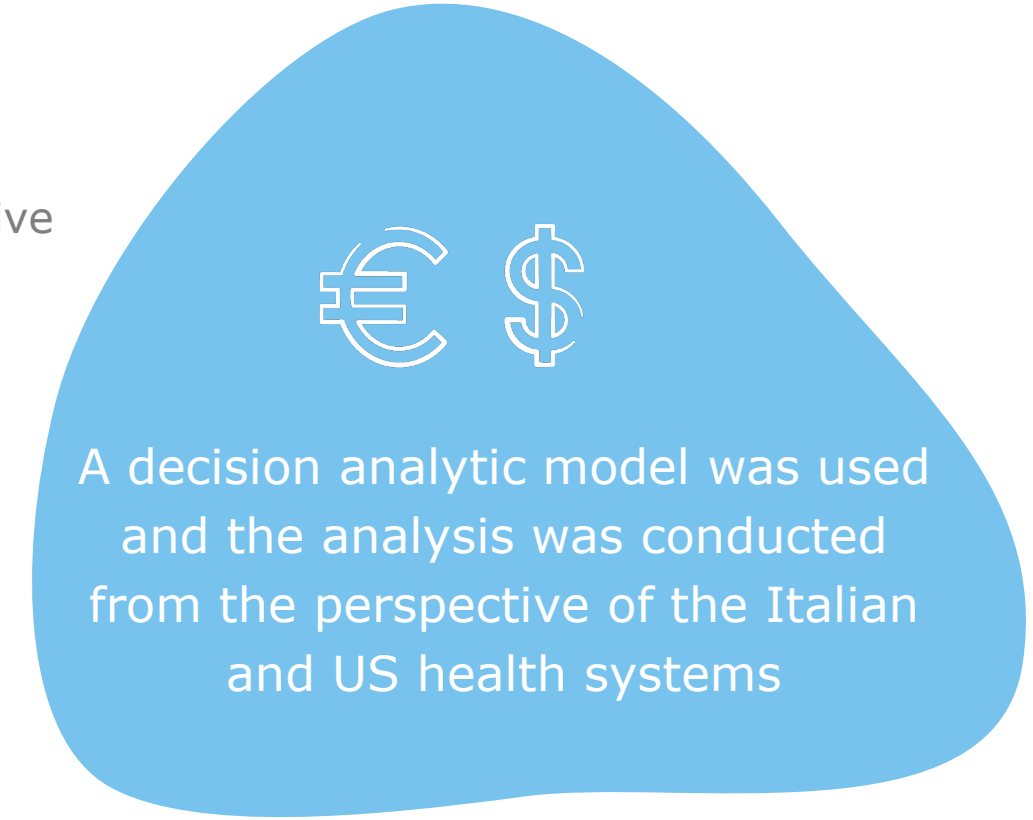
Conclusion

ALLEVYN LIFE Dressing plus standard preventive care
reduced sacral PU incidence in elderly patients
with hip fracture compared with standard preventive care alone;
adhesion of the dressing also kept consumption to a minimum

Forni C and Searle R. 2020[20]

Study overview

- Economic evaluation to determine whether ALLEVYN LIFE Dressing alongside standard preventive care for PUs in older patients with hip fractures is a cost-effective strategy compared with standard preventive care alone
- PU incidence data were derived from a randomized controlled trial comparing ALLEVYN LIFE Dressing plus standard preventive versus standard preventive care alone[19]



Forni C and Searle R. 2020[20]

Cost effectiveness – Italian healthcare perspective

From the **Italian healthcare perspective**, compared with standard preventive care alone, ALLEVYN LIFE Dressing plus standard preventive care demonstrated:

11 PUs avoided
based on a cohort of 100 patients, with an overall cost reduction of **€73,264**

Expected cost saving of **€733 per patient***

37–69% reduction in per patient cost
of PU treatment due to greater effectiveness

*Based on cost per patient episode of PU (2017 costs): €6,878

Forni C and Searle R. 2020[20]

Cost effectiveness – US healthcare perspective

From the **US healthcare perspective**, compared with standard preventive care alone, ALLEVYN LIFE Dressing plus standard preventive care demonstrated:

11 PUs avoided
based on a cohort of 100 patients, with an overall cost reduction of **$83,961**

Expected cost saving of **$840 per patient***

36–68% reduction in per patient cost of PU treatment due to greater effectiveness

*Based on cost per patient episode of PU (2017 costs): $8,014

Forni C and Searle R, 2020[20]

Conclusion

Adding ALLEVYN LIFE Dressings to standard preventive care was estimated to be **cost saving** and **more effective** at helping to prevent PUs in elderly patients with hip fractures than using standard preventive care alone

Beeckman D, *et al*. 2020[21]

Study overview

- Independent, pragmatic, randomised controlled open-label trial conducted at eight Belgian hospitals, to assess whether multilayer silicone foam dressings can help prevent hospital-acquired PUs (HAPUs)
- Dressings applied and changed according to manufacturers' instructions (study period up to 14 days)

Control group (n=546) received standard preventive care alone

- Risk, daily skin and nutritional assessments, tailored repositioning, heel offloading and skin care

In addition to standard preventive care, the pooled experimental group received either:

ALLEVYN LIFE Dressing (n=542)

- ALLEVYN LIFE Dressing on both hips
- ALLEVYN LIFE Heel on both heels
- ALLEVYN LIFE Sacrum on the sacral area

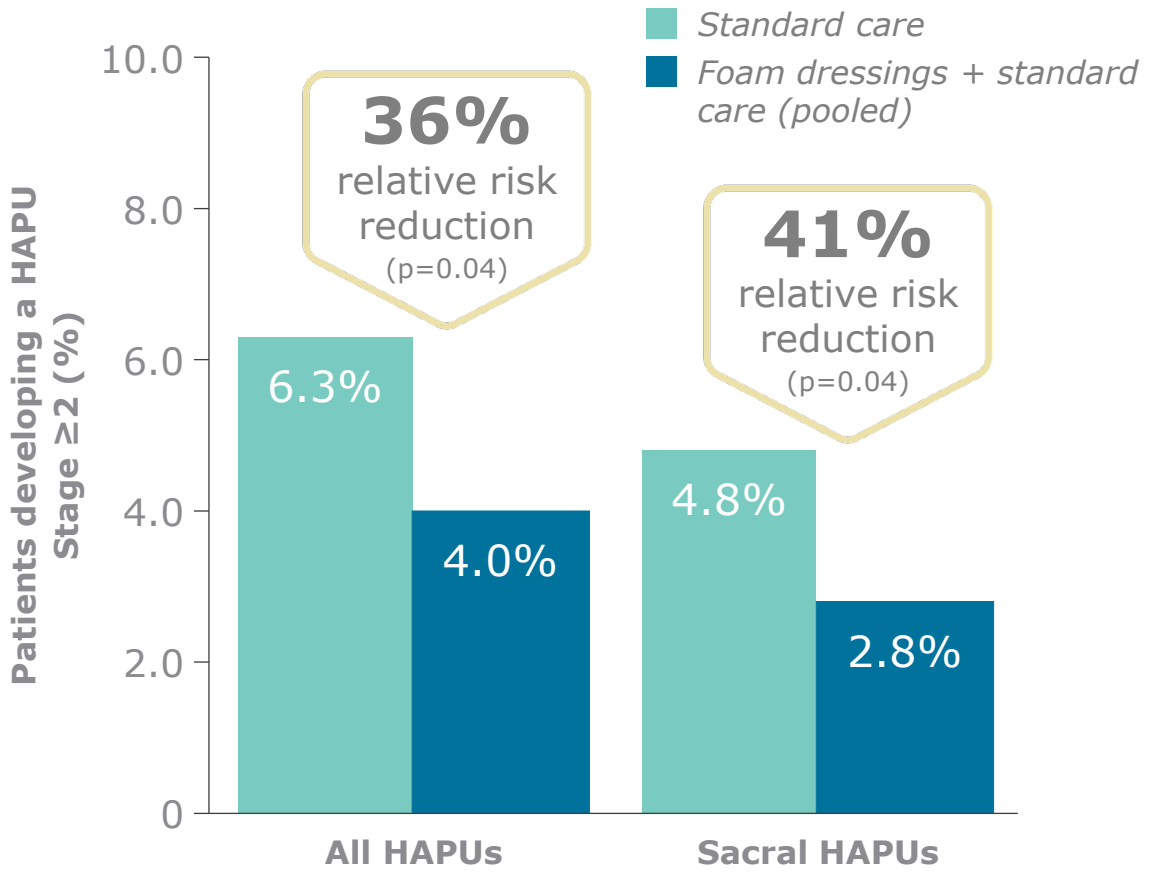
Mepilex™ Border Dressings (Mölnlycke, Sweden; n=545)

- Mepilex™ Border Dressing on both hips
- Mepilex™ Border Heel on both heels
- Mepilex™ Border Sacrum on the sacral area

Beeckman D, *et al*. 2020[21]

Incidence of HAPUs

Across hospital wards, compared with standard care alone, the addition of foam dressings resulted in:



- 24% relative risk reduction in heel HAPUs (1.4 vs 1.9% p=0.49)
- Only one patient developed a HAPU at the hip in the experimental group

No differences in effectiveness between ALLEVYN LIFE Dressing and Mepilex™ Border Dressing
(exploratory data analysis)

Beeckman D, *et al*. 2020[21]

Conclusion

Addition of ALLEVYN LIFE Dressing or Mepilex™ Border Dressing to standard care **significantly reduced** the incidence of HAPUs (stage ≥2) in at-risk patients across hospital wards compared with standard care alone. **No difference** in clinical effectiveness was observed between the two foam dressings

Stankiewicz, *et al*. 2019[22]

Study overview

A randomised, cluster-controlled clinical trial comparing the incidence of sacral PIs (≥Stage 1) with ALLEVYN LIFE Sacrum Foam Dressing and Mepilex™ Border Sacrum dressing (Mölnlycke, Sweden), both used in addition to standard preventive care,* at a hospital in Australia

- ICU patients who could have a dressing applied for ≥24hrs without repeated dislodgement or soiling (≥3 times) were enrolled within 48hrs of admission
- Patients were allocated to each dressing type in 3-month alternating clusters (three cycles per product) to minimise the impact of seasonal variation on admissions
- ICU nursing staff were educated on PI assessment before the study and supported by a nurse consultant during the study

302
adult patients
(ALLEVYN◇ LIFE Sacrum Dressing, n=129; Mepilex™ Border Sacrum dressing, n=173)

>95%
of patients had intact sacral skin on assessment; no patients had a PI on admission

*Standard preventive care included repositioning every 2–4hrs, specialised low air-loss beds and use of adjunct repositioning and turning aids

Stankiewicz, *et al*. 2019[22]

Sacral PIs, dressings used and integrity

There was no statistically significant difference between ALLEVYN LIFE Sacrum Dressing and Mepilex™ Border Sacrum dressing:

0.44 sacral PIs
per 100 dressing days
for both dressings

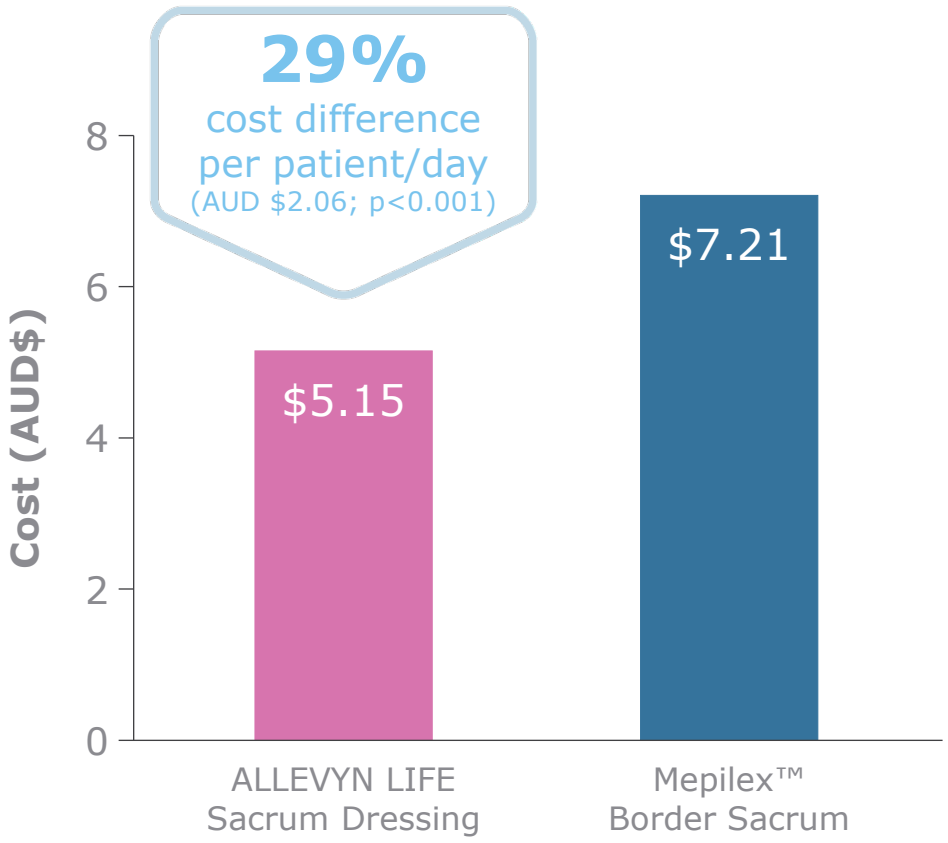
No patients with a PI on another body site at admission developed a sacral PI

0.5 dressings per patient per day
for both dressings

Product integrity
intact despite twice daily skin inspections
(85 vs 84%, respectively; p=0.69)

Stankiewicz, *et al*. 2019[22]

Cost of treatment per patient



Cost-effectiveness was defined as the mean cost of dressings per patient in each group divided by the proportion of patients without a sacral PI (cost of ALLEVYN LIFE Sacrum Dressing was AUD$10.29 and Mepilex™ Border Sacrum was AUD$14.42)

Cost per patient per day was significantly lower with ALLEVYN LIFE Sacrum Dressing than Mepilex™ Border Sacrum dressing (p<0.001)

Total dressing costs per patient were also significantly reduced (p<0.001)

Stankiewicz, *et al*. 2019[22]

Conclusion

ALLEVYN LIFE Sacrum Dressing was as effective as Mepilex™ Border Sacrum dressing at helping to **reduce the incidence of sacral PIs** and **provided significant cost savings when used with standard preventive care** in critically ill ICU patients

Austin M. 2019[23]
Study overview

- A quality improvement project, including a medical device related PIs (MDRPI) prevention bundle, in response to increased MDRPIs at six US hospitals (Cone Health, North Carolina, USA)
  - Mean MDRPI incidence increased from 21.6% in 2018 to 35.0% in the first two quarters of 2019
- MDRPI prevention initiatives adopted included:

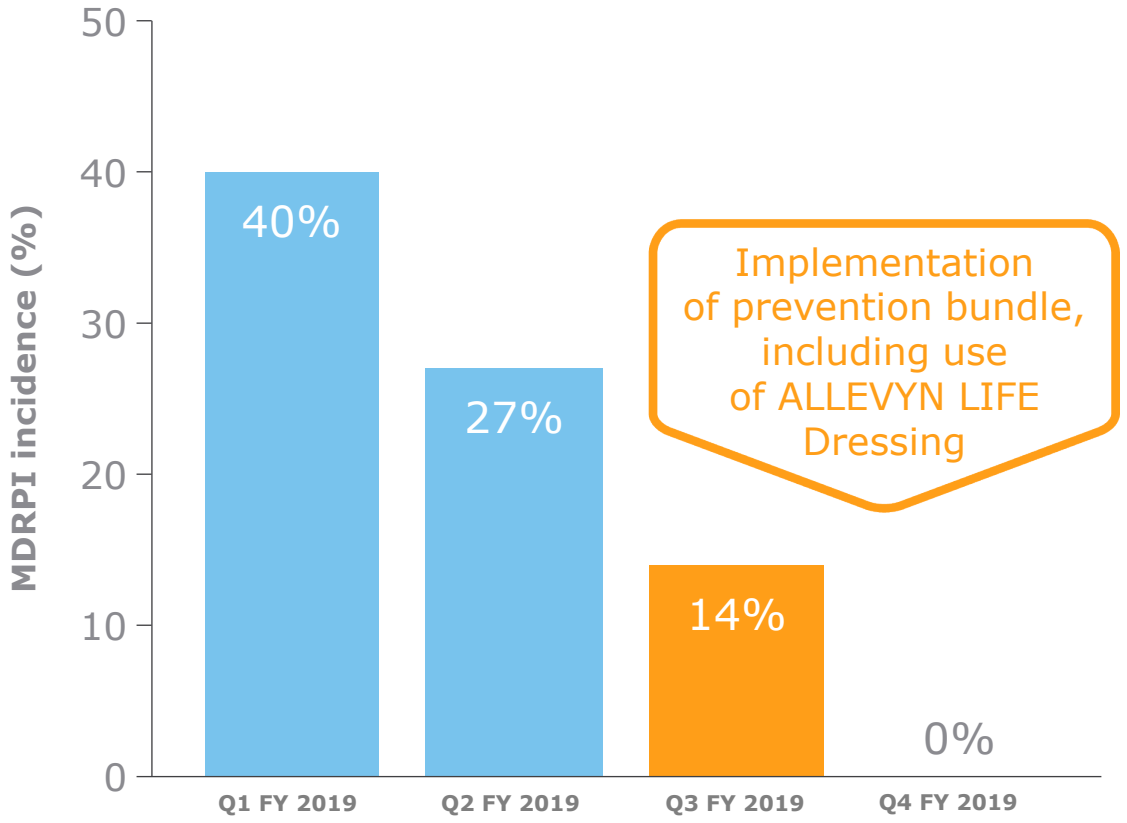
Interventions specifically for medical devices, eg:
- Use of ALLEVYN LIFE Dressings under medical devices
- Period assessment and repositioning
- Application of skin barrier film on otherwise exposed areas

Expansion of a **multi-disciplinary approach** for implementation

Adoption of the bundle in all hospital settings

Guidance was provided on use of ALLEVYN LIFE Dressings as part of the bundle

Austin M. 2019[23]
MDRPI and PI incidence



Incidence of MDRPIs during 2019, before and after implementation of a prevention bundle

After implementation of the prevention bundle, including use of ALLEVYN LIFE Dressings:

0% MDRPI incidence
in Q4 2019
(20% in financial year 2019)

0.8% PI incidence
in Q4 2019
(vs 2.3% in Q2 2019 before implementation)

FY = financial year

Austin M. 2019[23]
Conclusion

Implementation of an MDRPI prevention bundle, including guidance for use of ALLEVYN LIFE Dressings with medical devices, **helped to reduce MDRPI incidence** to zero across six US hospitals in Q4 2019

Lee C, *et al*. 2019[24]
Study overview

- Randomised controlled trial to assess whether use of ALLEVYN GENTLE BORDER Dressing can help maintain skin integrity
- Critically ill patients received standard preventive care alone (n=31) or ALLEVYN GENTLE BORDER Dressing (n=35) applied every 3 days to the sacrum (minimum ICU stay 48 hours)
- Subepidermal moisture of the sacrum, coccyx and buttocks was measured every 3 days using a moisture meter
  - Blanching erythema was assessed by visual inspection

Lee C, *et al*. 2019[24]

PI incidence and impaired skin integrity

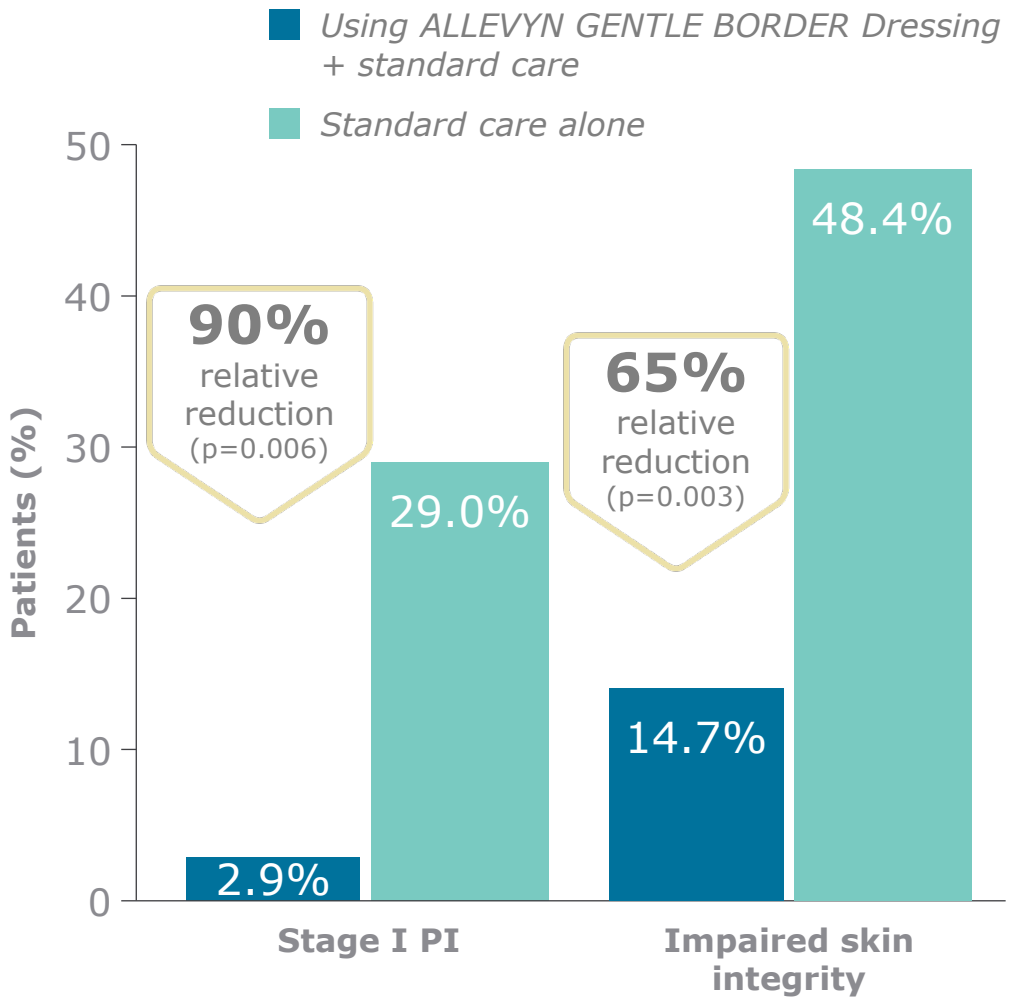
Compared with standard preventive care alone, the addition of ALLEVYN GENTLE BORDER Dressing resulted in:

Lower incidence of Stage I PIs

Reduced incidence of impaired skin integrity

Similar incidence of blanching erythema

(14.2 vs 19.4%; 5 vs 6 patients, respectively)



Lee C, *et al*. 2019[24]

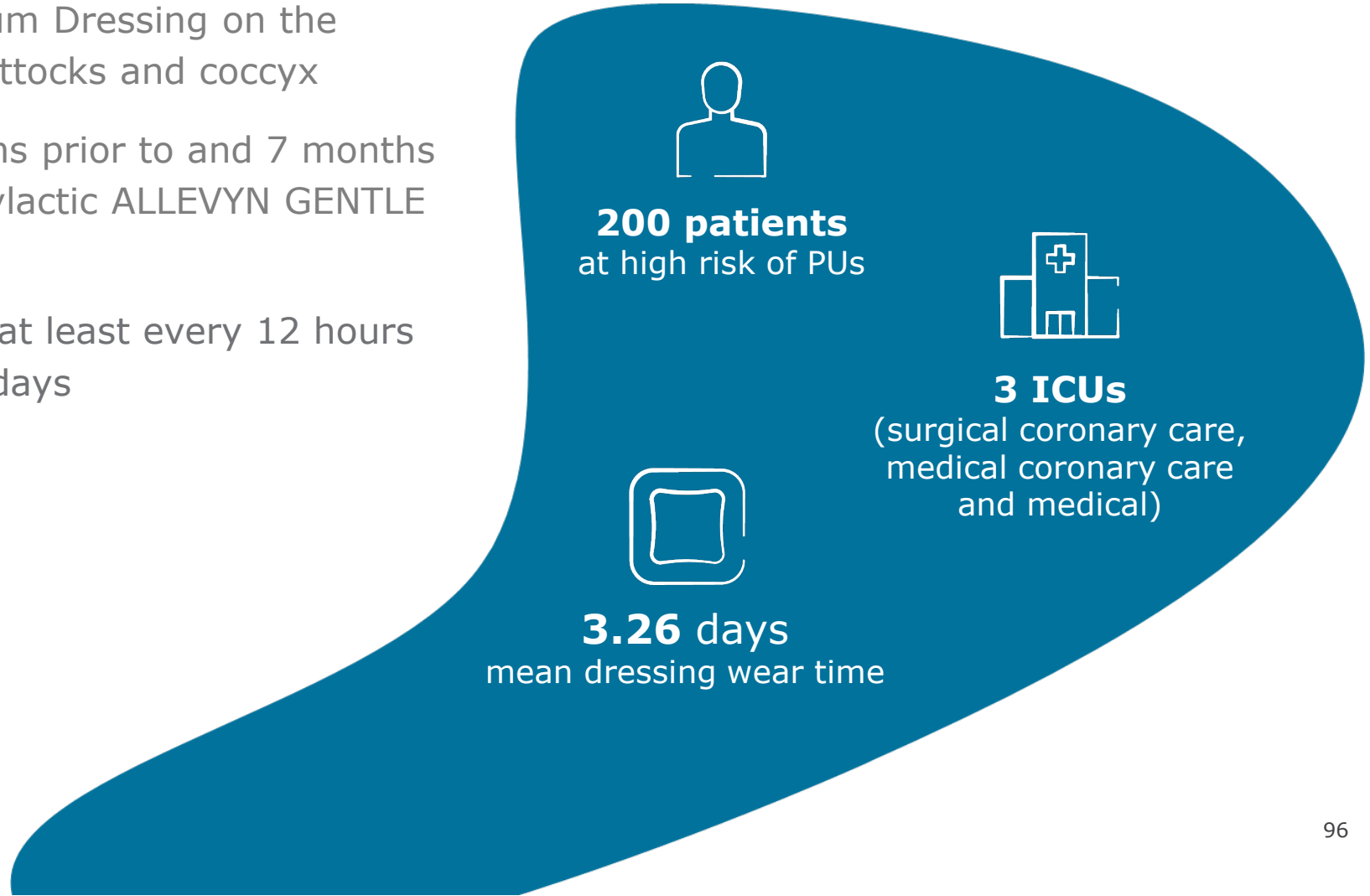
Conclusion

Use of ALLEVYN GENTLE BORDER Dressing in addition to standard preventive care helped to **significantly reduce the incidence of PIs** and impaired skin integrity in the sacral area compared with standard preventive care alone in critically ill ICU patients

Byrne, *et al*. 2016[25]

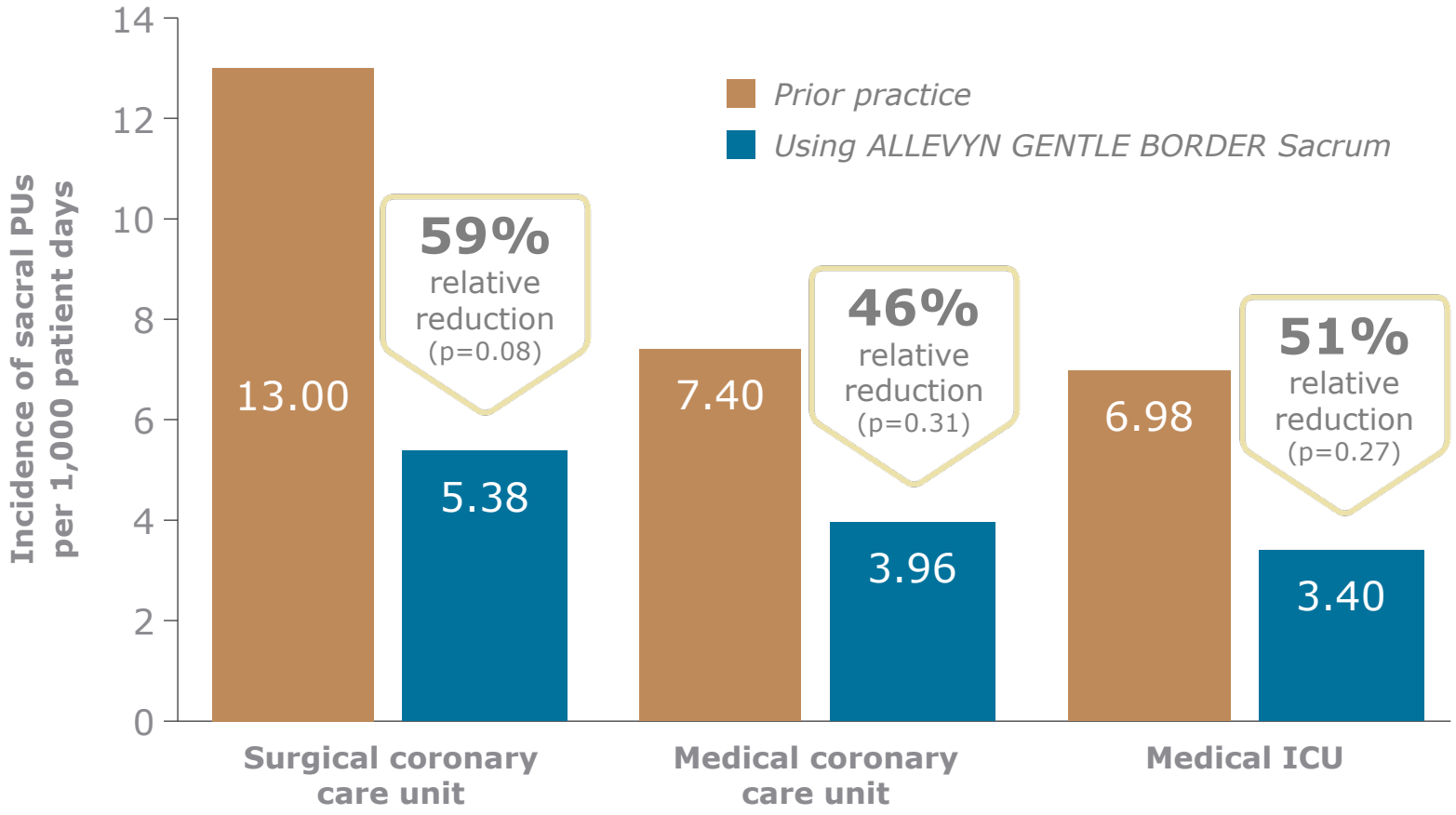
Study overview

- Prospective, observational study to determine the effect of ALLEVYN GENTLE BORDER Sacrum Dressing on the incidence of PUs on the sacrum, buttocks and coccyx
- PU incidence was assessed 7 months prior to and 7 months following the introduction of prophylactic ALLEVYN GENTLE BORDER Dressing use
- Nurses performed skin inspections at least every 12 hours and changed the dressing every 3 days



Byrne, *et al*. 2016[25]
Incidence of PUs

ALLEVYN GENTLE BORDER Sacrum Dressing reduced the incidence of sacral PUs in all three ICUs compared with prior practice



Positive nurse ratings for:

- Wear time
- Patient comfort
- Safety
- Ease of application
- Removal and repositioning

Byrne, *et al*. 2016[25]

Conclusion

Prophylactic use of ALLEVYN GENTLE BORDER Sacrum Dressing helped to **reduce sacral PU incidence** in high-risk patients on all three ICUs compared with prior practice

Evidence summary: results from key studies

Wound management

With ALLEVYN◇ LIFE Dressing there was:

48.7% increase in mean wear time (from 3.5 to 5.2 days)[4]

42.6% reduction in mean weekly dressing change frequency (from 4.7 to 2.7 changes per week)[4]

>85 hours of nursing time were estimated to be released per week using ALLEVYN LIFE Dressing (166 visits per week)[4]*

64.4% reduction in dressing cost per patient per week with use of ALLEVYN LIFE Dressing (from £28.46 to £10.12)[3]

98% of nurses recommended ALLEVYN LIFE Dressing[4†]

90% of nurses rated ALLEVYN LIFE Dressing as 'good' to 'excellent'[4†]

PI prevention

71% reduction in sacral PI incidence with ALLEVYN LIFE Dressing[19]

36–69% estimated cost savings per patient with ALLEVYN LIFE Dressing[20]

Positive nurse ratings for wear time, patient comfort, safety, ease of application, removal and repositioning with ALLEVYN GENTLE Border Dressing[25]

*Across 83 wounds requiring ≥3 dressing changes per week; †Based on either n=103 or n=105 survey responses

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For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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