

WHAT IS A VCF?

THE BURDEN
OF A VCF

TREATMENT
OPTIONS

BKP

VP

MORTALITY RISK

ECONOMIC VALUE

BALLOON KYPHOPLASTY & VERTEBROPLASTY

VALUE SUMMARY



REFERENCES



WHAT IS A VERTEBRAL COMPRESSION FRACTURE?

WHAT IS A VCF?

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OSTEOPOROSIS

FRACTURE
TYPE

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INCIDENCE

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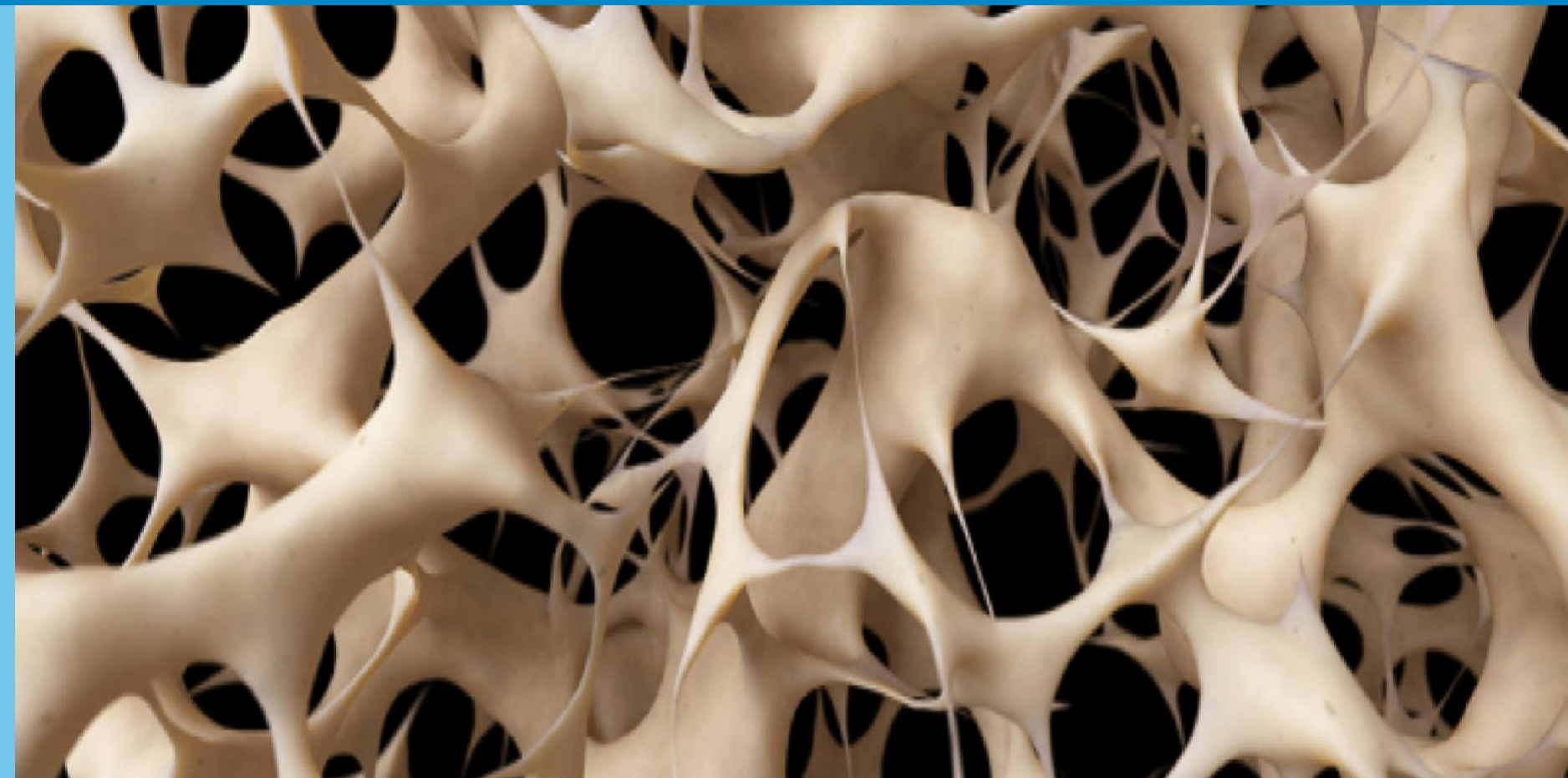
REFERENCES

A VERTEBRAL
COMPRESSION
FRACTURE
IS A COLLAPSE
OF A VERTEBRA
AND MAY BE DUE TO
OSTEOPOROSIS
TRAUMA
OR TUMOR

A vertebral compression fracture can occur suddenly. This can cause severe back pain.

The pain is most commonly felt in the middle or lower spine. It can also be felt on the sides or in the front of the spine.

The pain is sharp and "knife-like." Pain can be disabling.



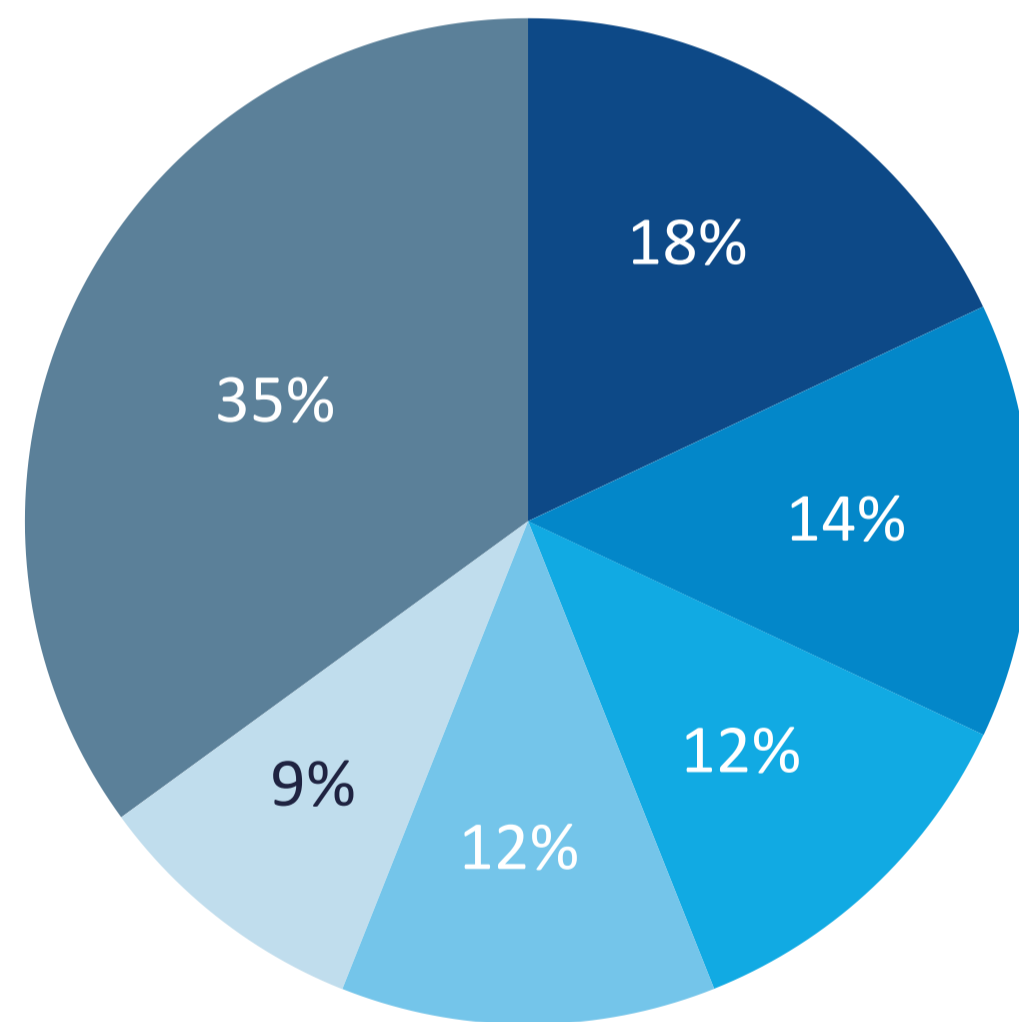
85%
OF VERTEBRAL
COMPRESSION
FRACTURES
ARE DUE TO
PRIMARY
OSTEOPOROSIS¹



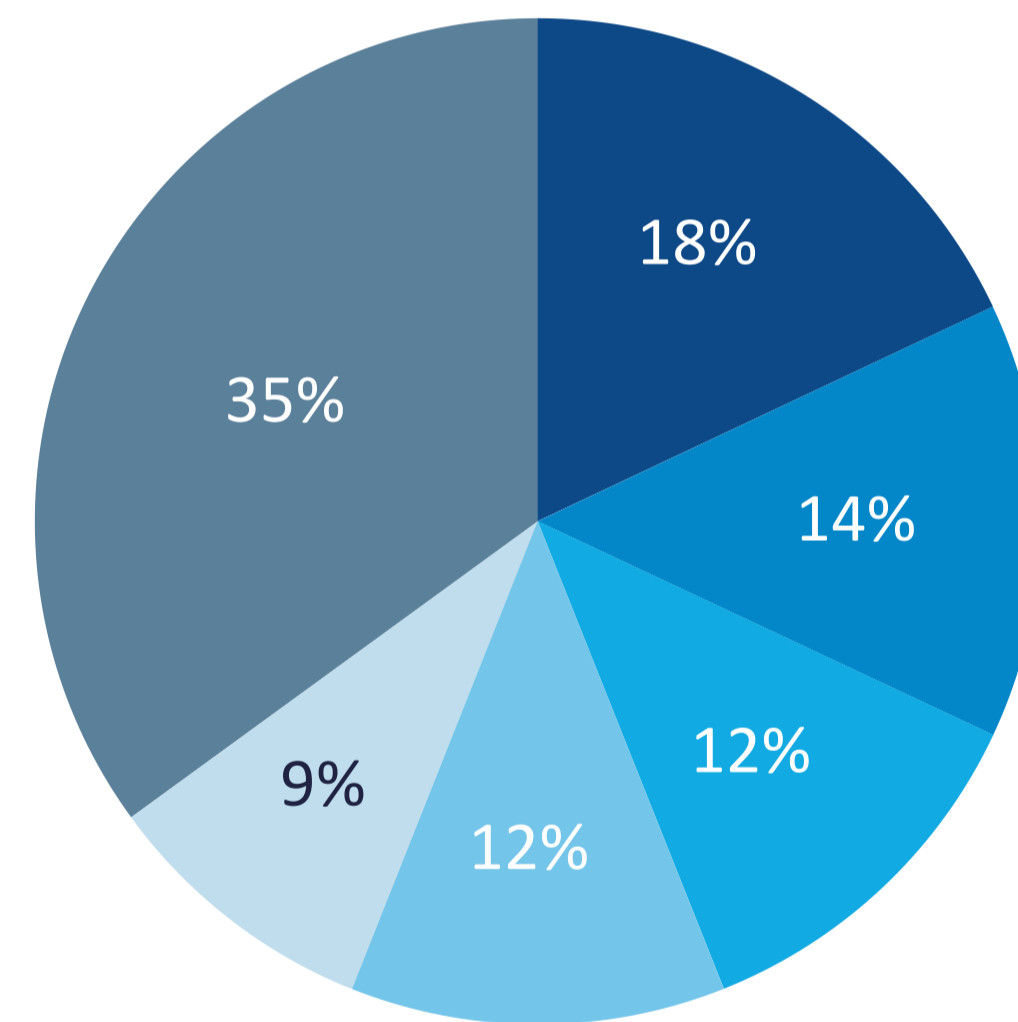
OSTEOPOROSIS

... is a disease in which the density and quality of bone are reduced. As bones become more porous and fragile, the risk of fracture is greatly increased. The loss of bone occurs silently and progressively. Often there are no symptoms until the first fracture².

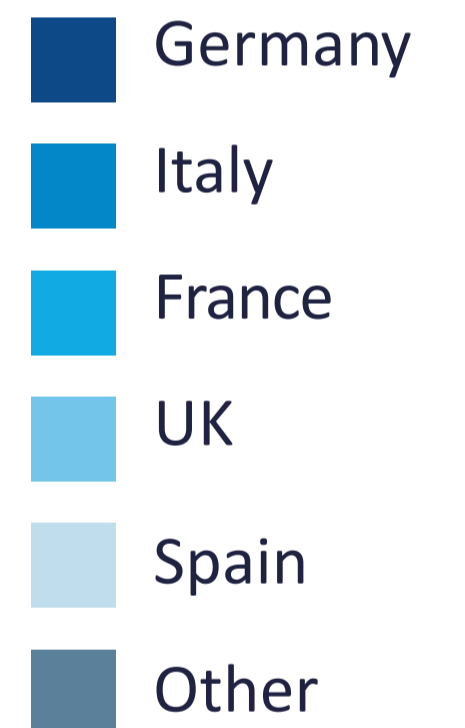
THE PREVALENCE DISTRIBUTION OF OSTEOPOROSIS IN THE EU AND THE 5 COUNTRIES WITH THE HIGHEST POPULATIONS IN 2010³:



22.0 million women in the EU have osteoporosis.



5.6 million men in the EU have osteoporosis.



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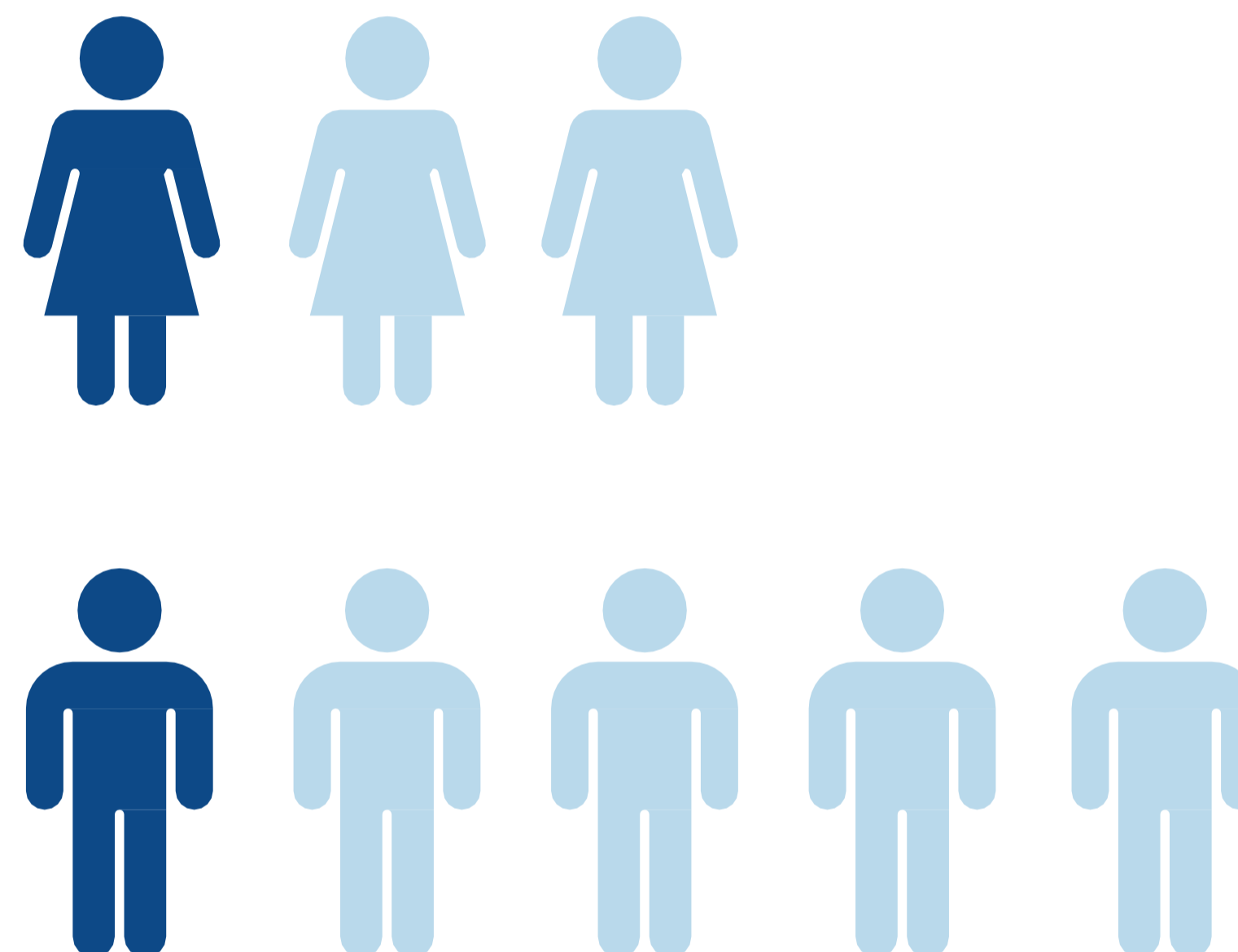
FRACTURE TYPE

VCF SECOND MOST COMMON FORM OF OSTEOPOROTIC FRACTURES

MOST COMMON FRACTURES



AROUND THE WORLD,
1 IN 3 WOMEN
AND 1 IN 5 MEN
ARE AT RISK OF AN
OSTEOPOROTIC
FRACTURE²



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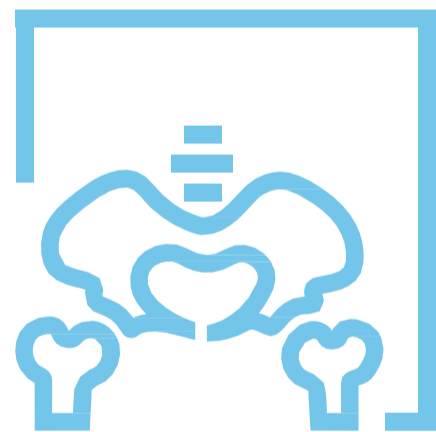
VCF SECOND MOST COMMON FORM OF OSTEOPOROTIC FRACTURES

FRACTURE RISKS

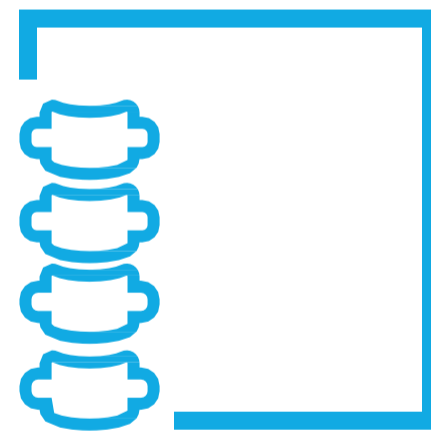


AN OSTEOPOROTIC FRACTURE IS ESTIMATED TO OCCUR **EVERY 3 SECONDS WORLDWIDE.**

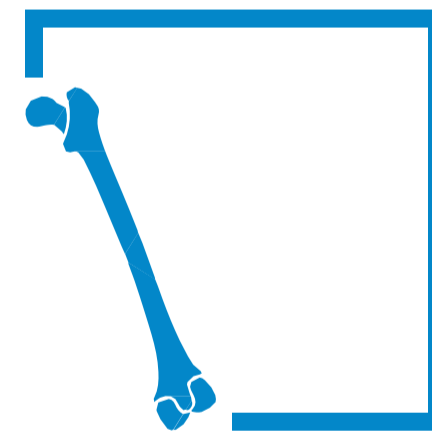
Every year, the most common fractures associated with osteoporosis occur at the hip, spine and wrist⁴.



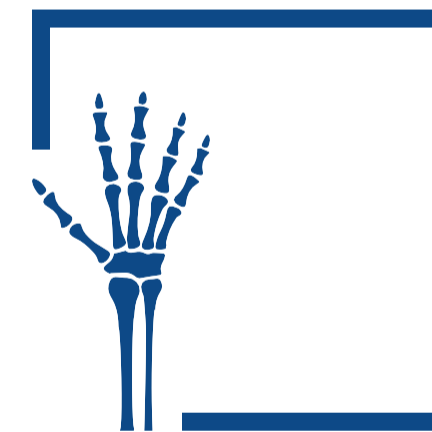
HIP
620,000



SPINE
490,000



PROXIMAL HUMERUS
250,000



FOREARM
574,000

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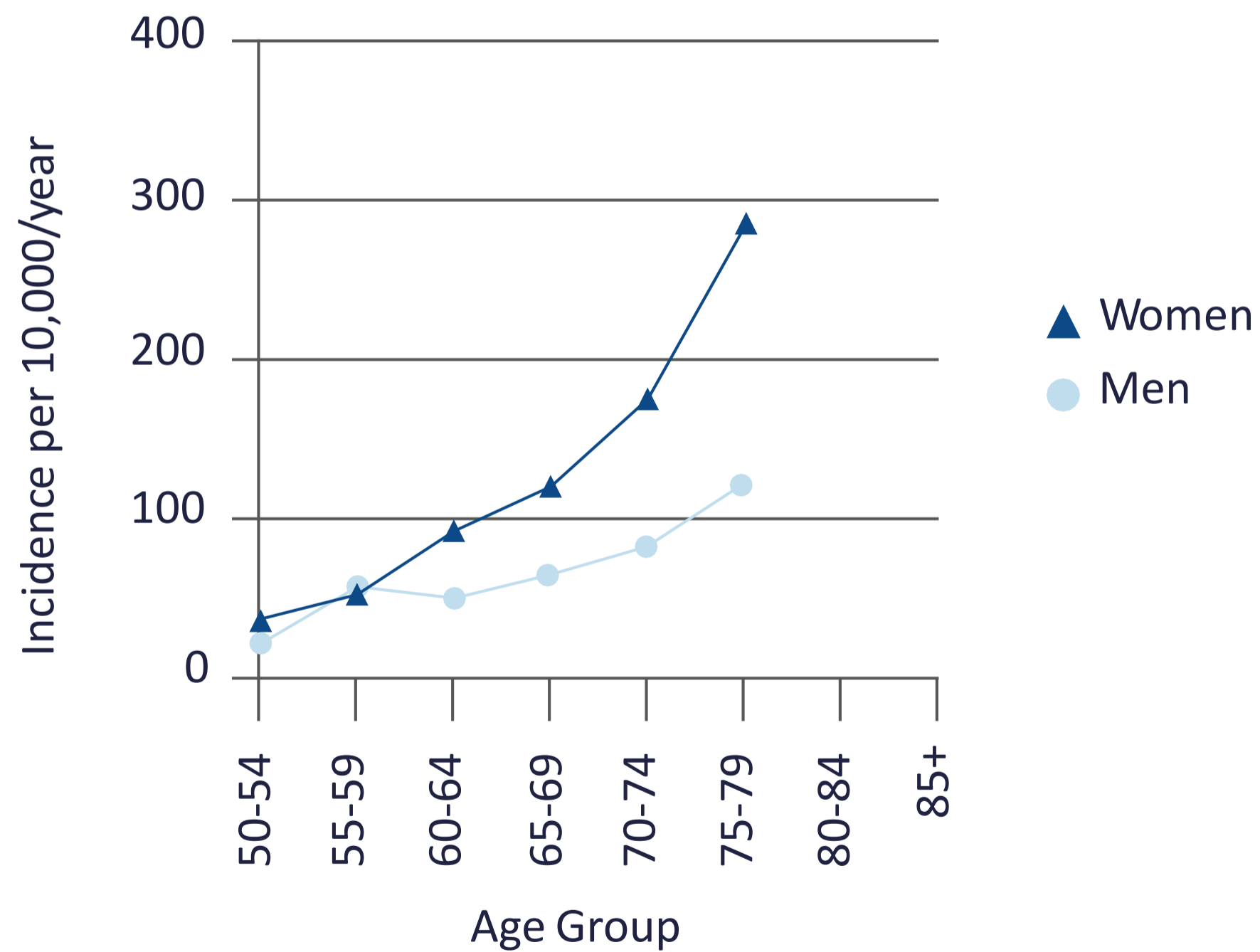
FRACTURE INCIDENCE RISING WITH AGE

DID YOU
KNOW?



The lifetime risk of a 50-year-old person to experience an osteoporotic fracture has been estimated at 13–22% for men and at 40–50% for women⁴.

INCIDENCE OF VERTEBRAL FRACTURE⁵



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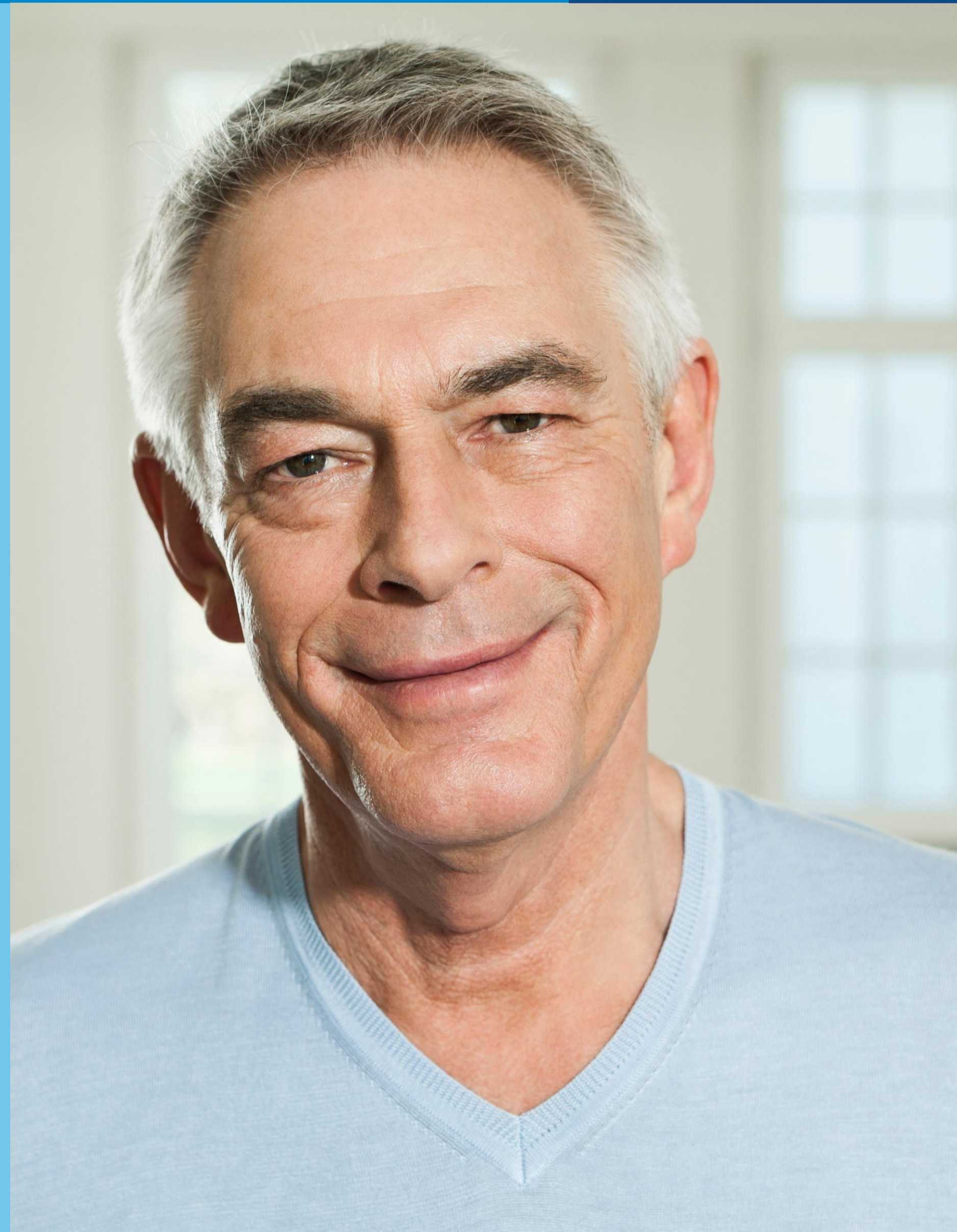
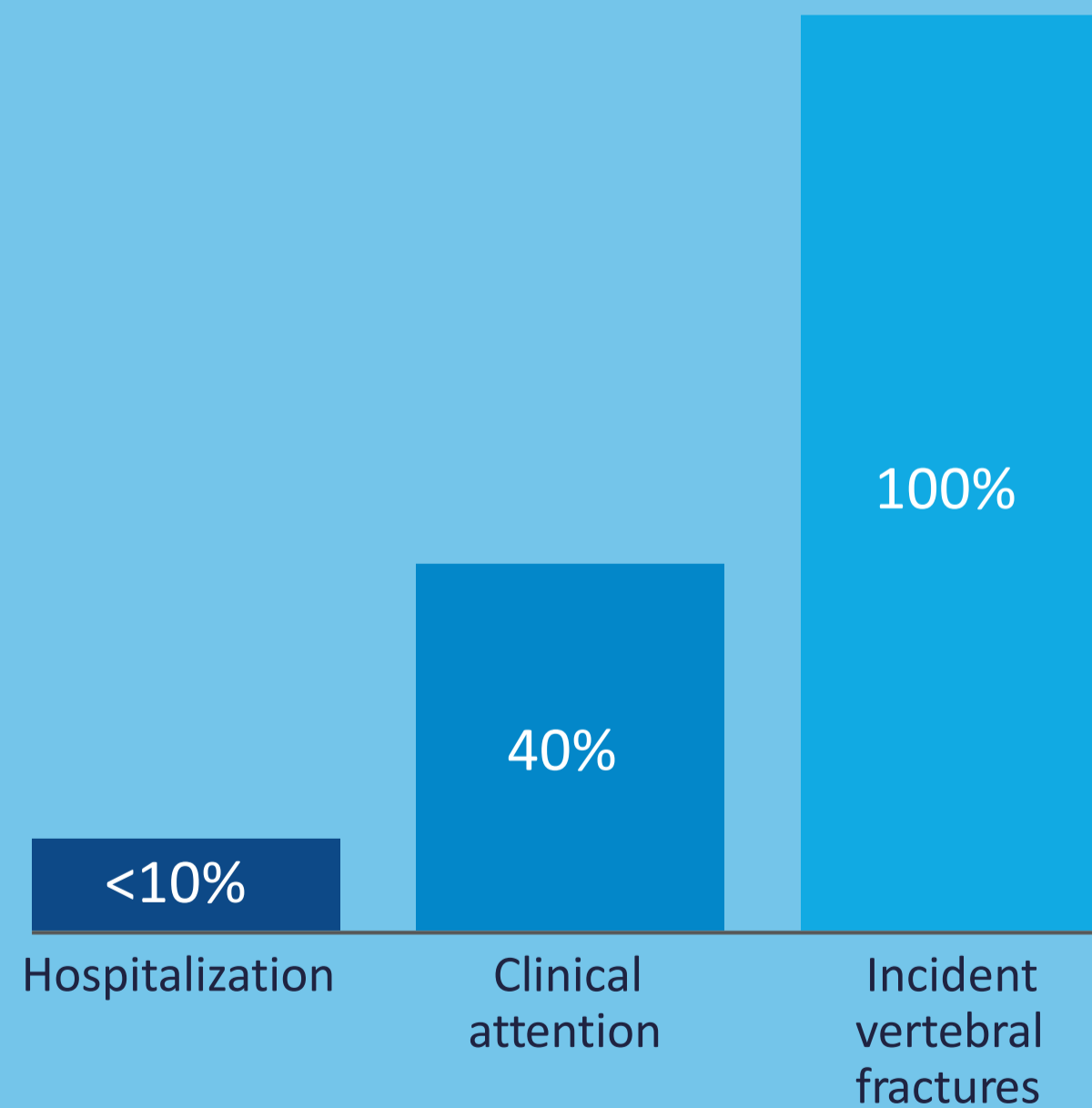


FRACTURE INCIDENCE RISING WITH AGE

FRACTURE RISKS



DID YOU KNOW THAT MOST OF THE VCF GO UNRECOGNIZED AT TIME OF OCCURRENCE?⁶



SIGNIFICANT HUMAN IMPACT

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BURDEN

ECONOMIC
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VERTEBRAL COMPRESSION FRACTURES CAN RESULT IN A RANGE OF PHYSICAL COMPLICATIONS:

- Spinal deformity, which further increases future fracture risk
- Significant ongoing quality of life decreases mainly by reducing physical functioning
- Increased morbidity, described as “downward spiral”
- Increased mortality
- Height loss.



SIGNIFICANT HUMAN IMPACT

LOSS OF QUALITY OF LIFE AFTER UNTREATED VCF

SIGNIFICANT HUMAN IMPACT OVERVIEW



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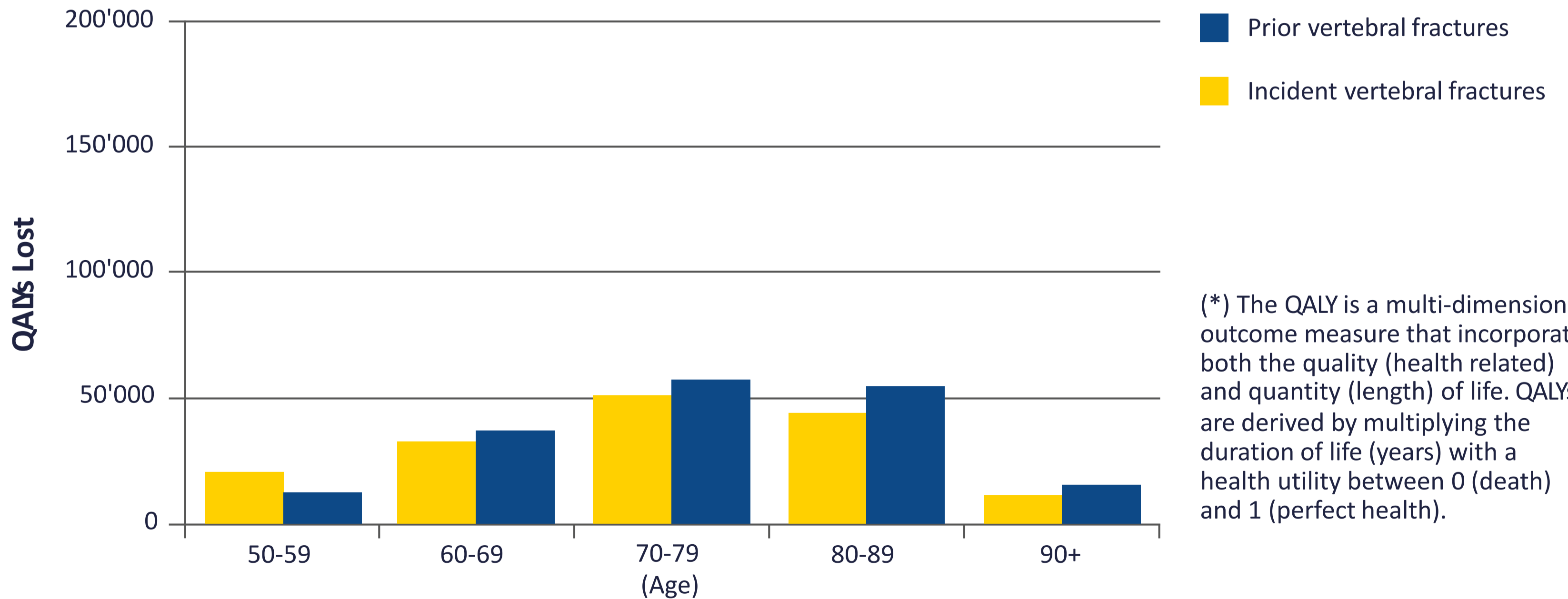
ECONOMIC VALUE

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Over 59 years of age, quality of life is always reduced.

AGE DISTRIBUTION (%) OF QALYS* LOST EU IN 2010
ADAPTED FROM HERNLUND ET AL. 2013³



(*) The QALY is a multi-dimensional outcome measure that incorporates both the quality (health related) and quantity (length) of life. QALYs are derived by multiplying the duration of life (years) with a health utility between 0 (death) and 1 (perfect health).

SIGNIFICANT HUMAN BURDEN

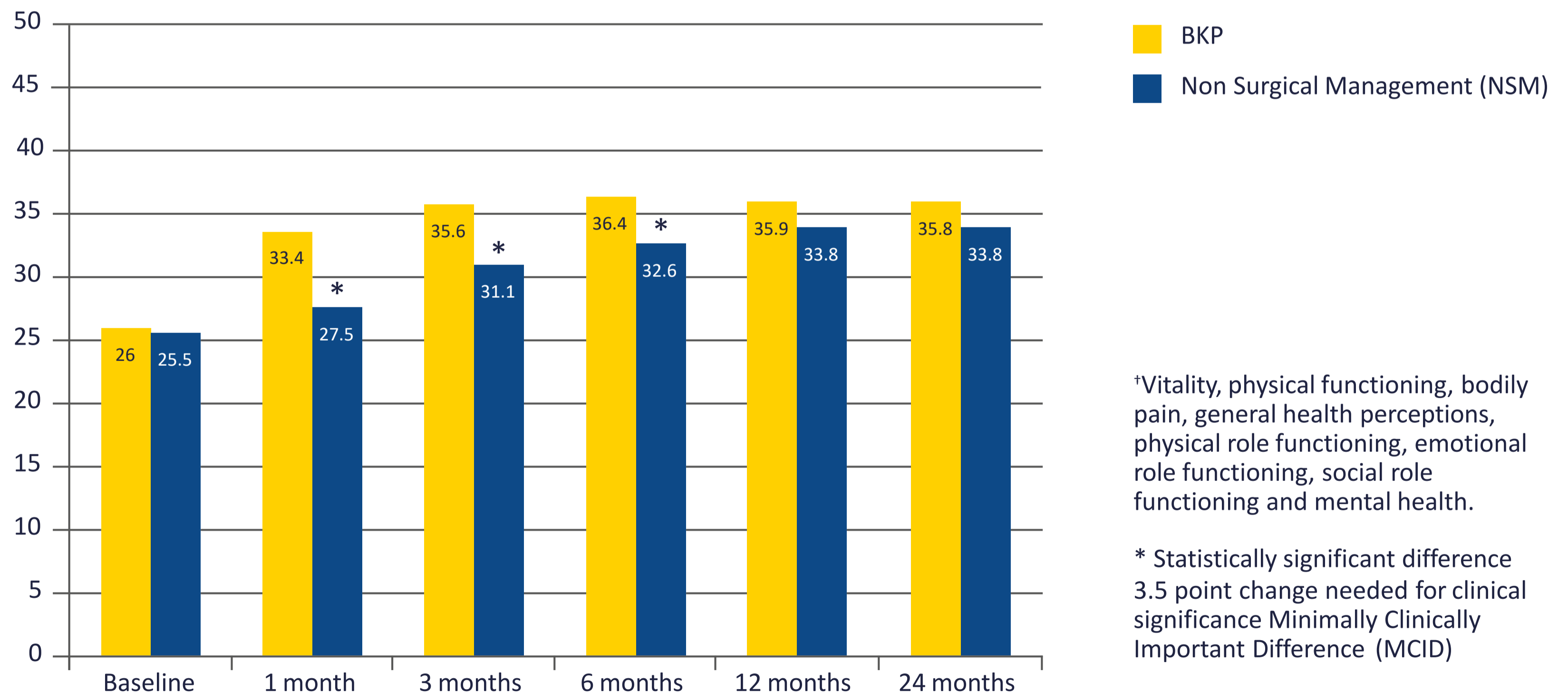
VCF IMPACT ON PAIN AND DISABILITY

SIGNIFICANT HUMAN IMPACT OVERVIEW



The Short Form (36) Health Survey is a 36-item, patient-reported survey of patient health, and measures multiple functionings[†].

SF-36 PHYSICAL COMPONENT SCORE¹¹



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SIGNIFICANT HUMAN BURDEN

VCF IMPACT ON DEFORMITY

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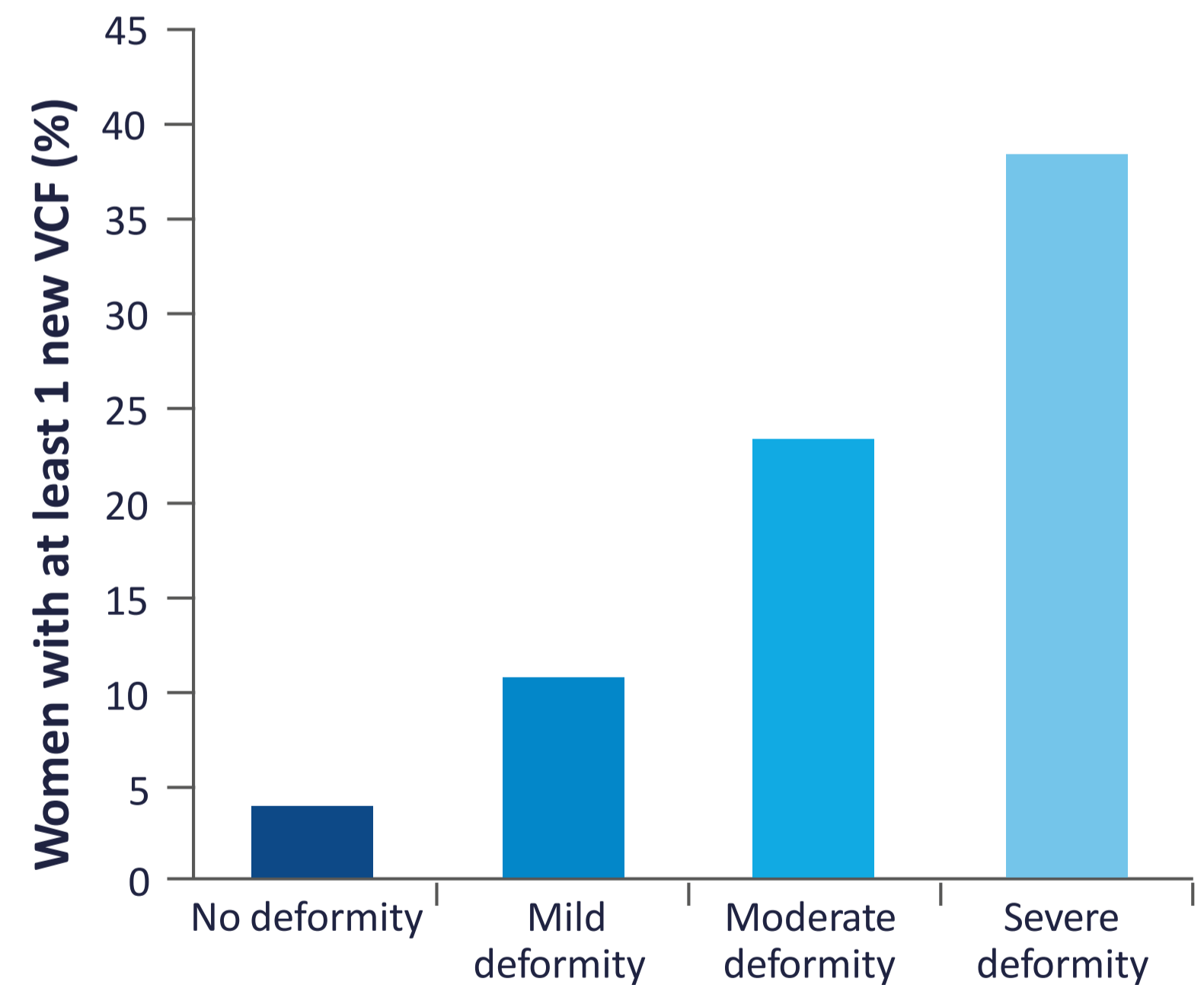
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**5-FOLD
INCREASE IN RISK
OF SUBSEQUENT
SPINE FRACTURE¹**
**2- TO 3-FOLD
INCREASE IN RISK
FOR FRACTURES AT
OTHER SITES^{2,3}**

Untreated spinal fractures often result in irreversible spinal deformity with abnormal curvature (kyphosis) – which in turn increases future fracture risk⁷.



VCF ECONOMIC BURDEN

COST COMPARISON VCF vs VCF FREE PATIENTS

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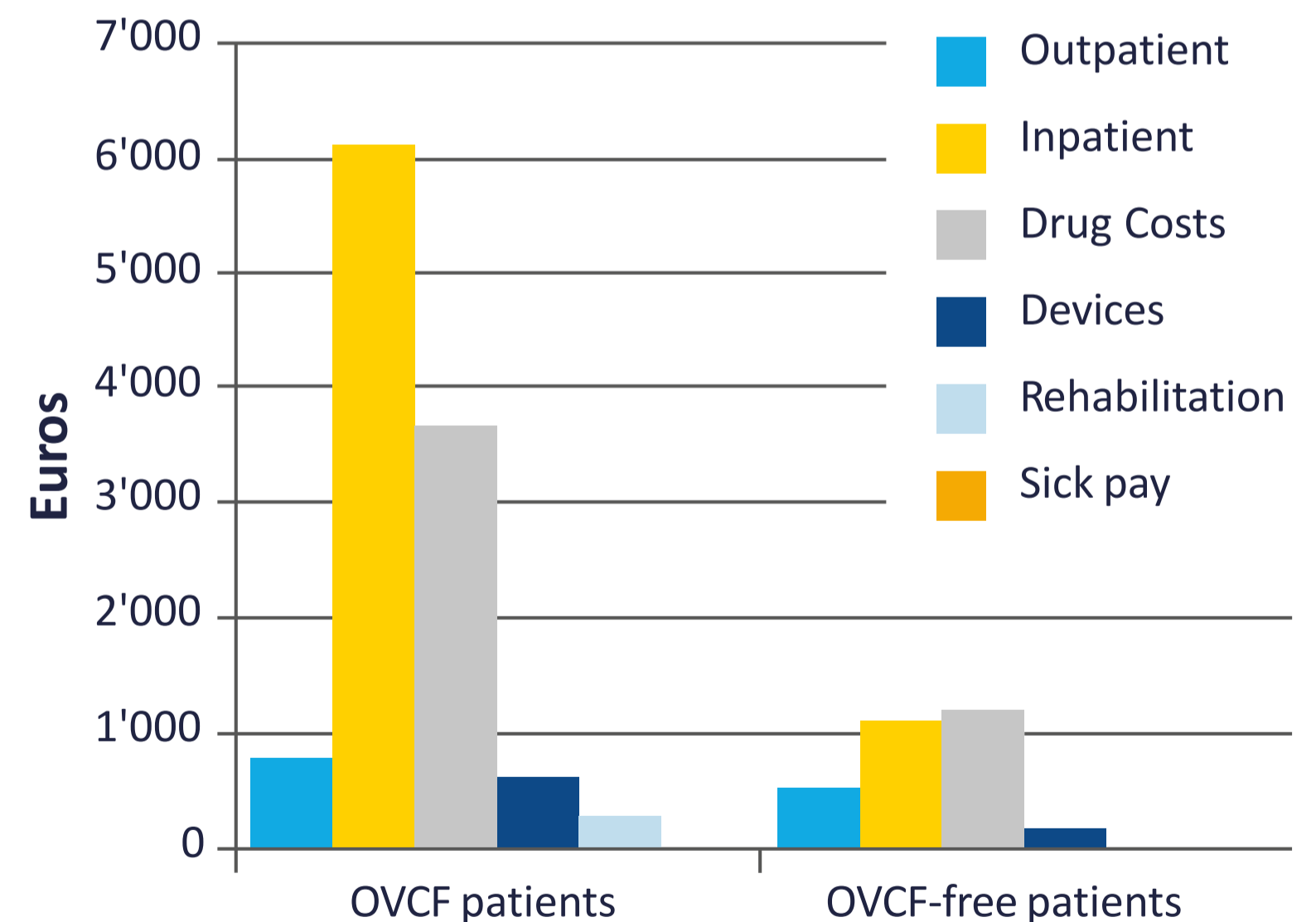


IT HAS BEEN ESTIMATED THAT HEALTH COSTS FOR PATIENTS EXPERIENCING AT LEAST ONE CASE OF VCF AND FOLLOWED FOR ONE YEAR IS ABOUT **4 TIMES HIGHER** THAN THOSE OF VCF-FREE PATIENTS (€ 11,435 VS € 3,235)⁴

In 2005, the European Union annual cost of fractures related to osteoporosis pegged at euro 37.0 billion, expected to increase by 25 % in 2025 .³

TOTAL ALL CAUSE COST COMPARISON BETWEEN OVCF AND OVCF-FREE PATIENTS

ADAPTED FROM LANGE ET AL 2014⁴



TREATMENT OPTIONS FOR OVCF

BKP, VP, NSM

STUDY



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There are 3 different ways to treat a VCF. First line of treatment is usually a Non-Surgical Management method, the Vertebroplasty or Balloon Kyphoplasty.

	NSM 	VP 	BKP 
Principle	Bed Rest, bracing, physiotherapy, medication	Bone cement is injected into the vertebra to stabilize	Use of a balloon in the vertebra to restore kyphotic angle and then cement injection
Pain Relief	Over time Some	Immediate Most (1 year) ⁹	Immediate Most (2 years) ⁹
Spinal Stabilisation	Not satisfactory	Yes	Yes
Corrects kyphosis	No	No	Yes



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BETWEEN 2005 AND 2008 858,978 PEOPLE WERE DIAGNOSED WITH A VCF IN THE UNITED STATES¹⁰

Kyphoplasty patients have a **34% greater** adjusted life expectancy than vertebroplasty patient

Patients being treated by BKP/VP have **43% less mortality risk** than those treated by non-surgical management



BALLOON KYPHOPLASTY

THE POWER OF THE BALLOON

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KYPHOPLASTY INVOLVES INSERTING A BALLOON-LIKE DEVICE (TAMP) INTO THE VERTEBRAL BODY, USING LOCAL OR GENERAL ANAESTHETIC VIA TWO SMALL BILATERAL INCISIONS IN THE SKIN



1. Fractured vertebra



2. Balloon inserted into vertebra



3. Balloon inflated to lift endplates



4. Cavity created in vertebra



5. Bone cement injected into cavity



6. Internal cast stabilizes fracture



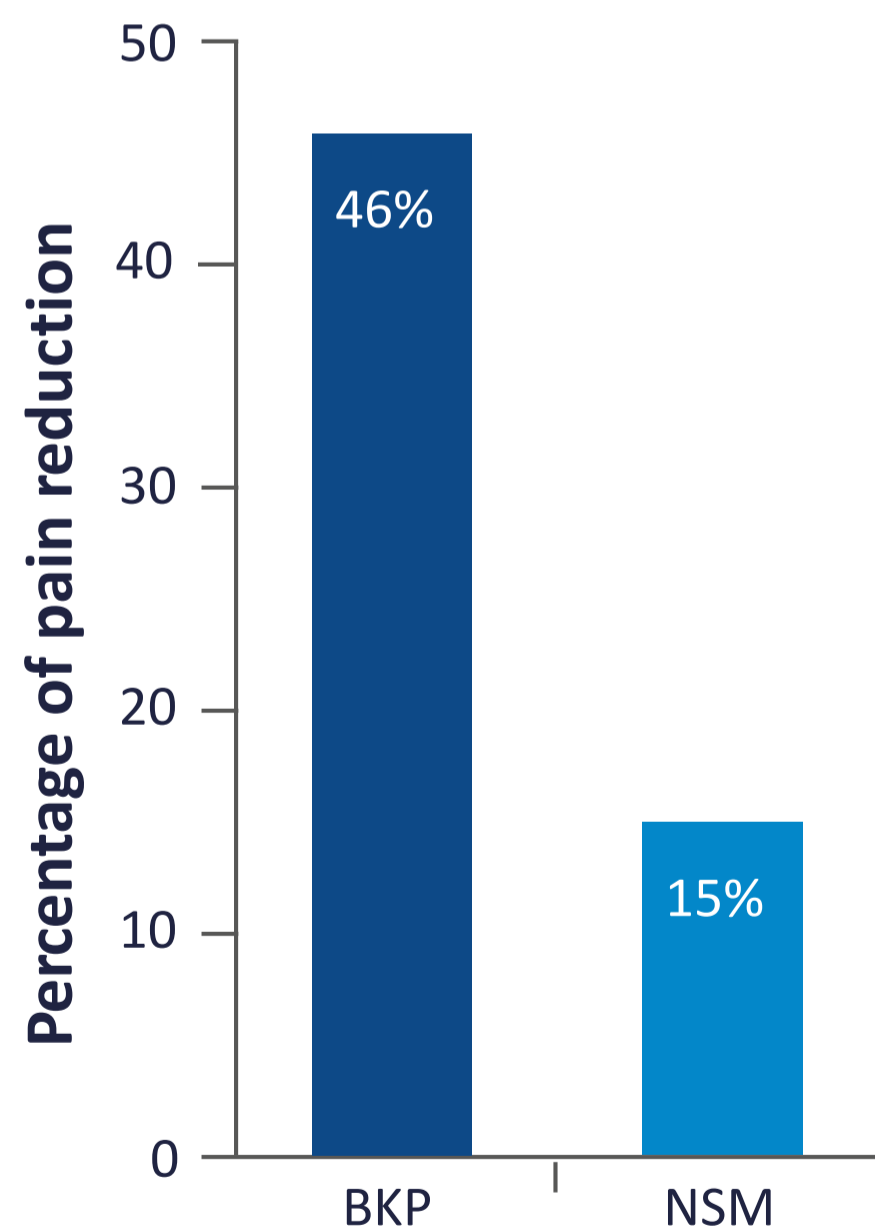
CLINICAL EVIDENCE

BKP COMPARED TO NSM: SUSTAINED PAIN RELIEF

**3 TIMES
MORE PAIN
REDUCTION
AT 1 WEEK
VS. NSM¹²**

For patients with VCFs Intervention treatment like Kyphon™ Balloon Kyphoplasty, provides significant benefits.

RAPID AND SUSTAINED PAIN RELIEF¹¹⁻¹²



Pain scores showed statistically significant improvement in the BKP group vs. NSM at 1 week ($p < 0.001$) and improvement was maintained through 2 years ($p = 0.009$)¹²

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CLINICAL EVIDENCE

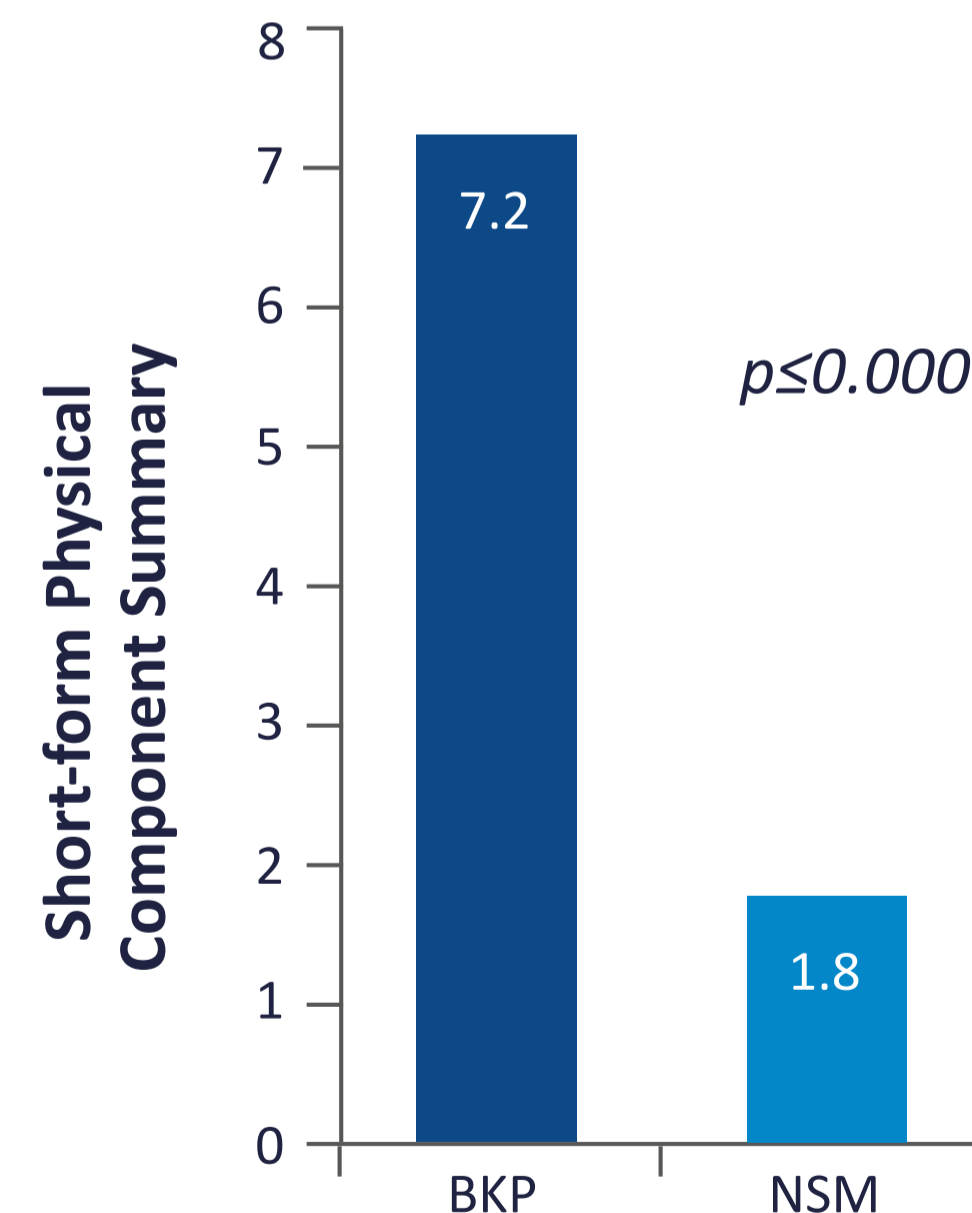
BKP COMPARED TO NSM: IMPROVED QUALITY OF LIFE

4 TIMES MORE IMPROVEMENT IN QUALITY OF LIFE AT 1 MONTH VS. NSM¹¹

Significantly improved quality of life
when averaged across 2 years vs. NSM¹²

For patients with VCFs Intervention treatment like Kyphon™ Balloon Kyphoplasty, provides significant benefits.

ENHANCED QUALITY OF LIFE¹¹⁻¹²



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CLINICAL EVIDENCE

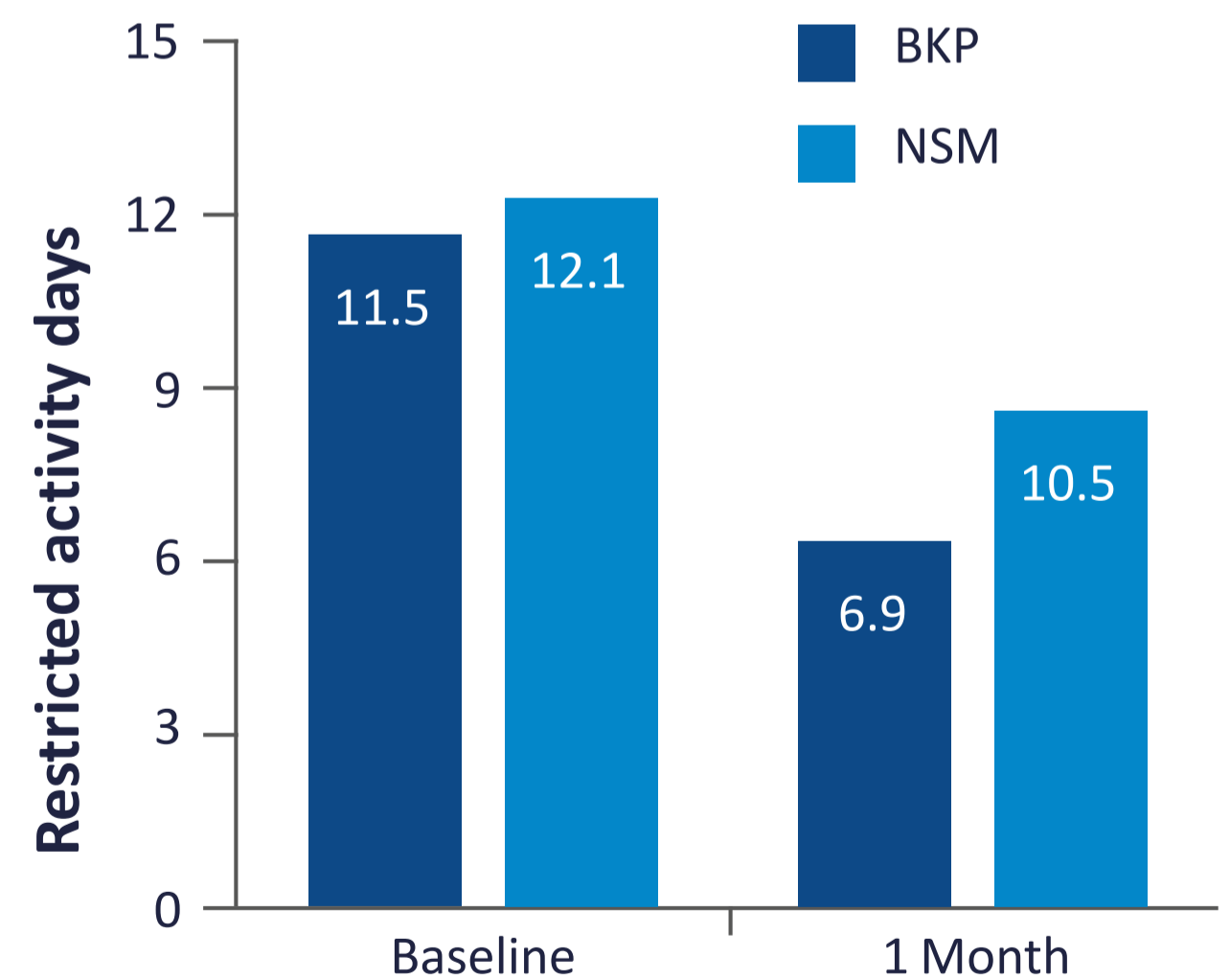
BKP COMPARED TO NSM: IMPROVED MOBILITY

**5 FEWER
DAYS OF
RESTRICTED
ACTIVITY
AT 1 MONTH
VS. NSM¹²**

**136 MORE
DAYS OF
ACTIVITY
GAINED
AT 2 YEARS
VS. NSM¹²**

- BKP has been shown to restore vertebral height¹³
- Height improvement with BKP was maintained at 12 and 36 months
- Vertebral height in control (NSM) patients was further reduced.

IMPROVED MOBILITY¹¹⁻¹²



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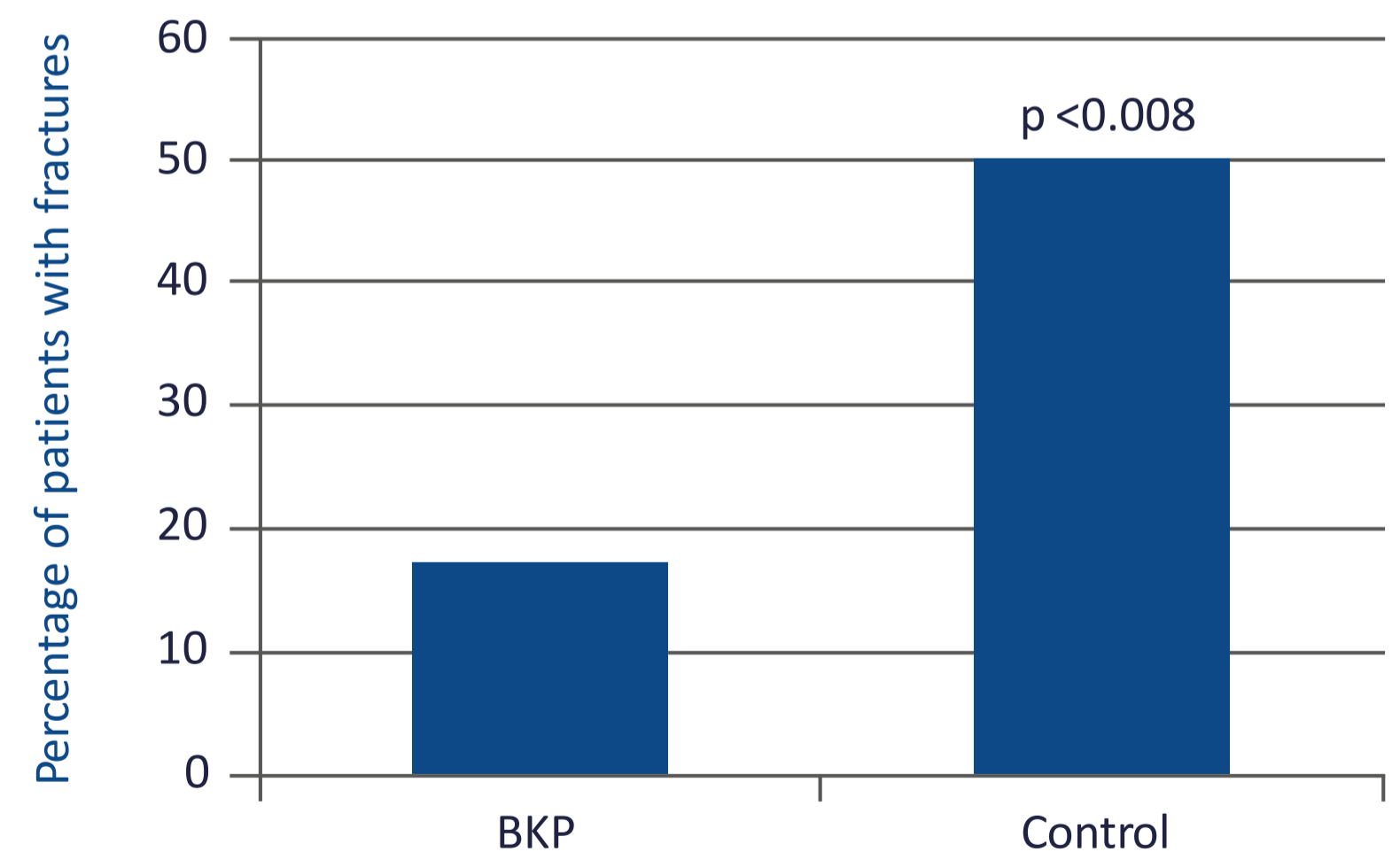
CLINICAL EVIDENCE

BKP COMPARED TO NSM: SUBSEQUENT FRACTURES

**3 TIMES
LESS
FRACTURES**

- BKP prevents subsequent fractures.
- Prospective controlled studies have shown that the subsequent vertebral fracture risk is significantly lower with BKP compared to NSM¹⁴⁻¹⁷.

SUBSEQUENT NEW FRACTURE RATES BKP VS.
NSM IN OSTEOPOROSIS¹⁶



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BALLOON KYPHOPLASTY

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BKP IS A MINIMALLY
INVASIVE TREATMENT
THAT HAS BEEN
REPORTED TO
REDUCE PAIN
CAUSED BY VCFS,
PARTIALLY RESTORE
LOSS OF VERTEBRAL
HEIGHT AND IMPROVE
FUNCTIONS AND QUALITY
OF LIFE (QOL)^{1,2}



VERTEBROPLASTY

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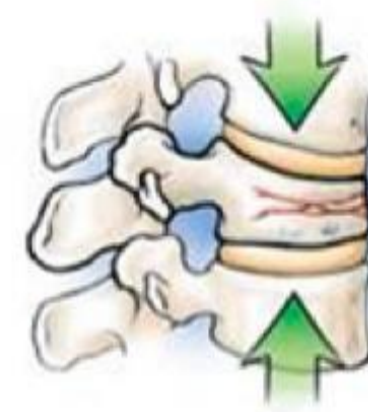
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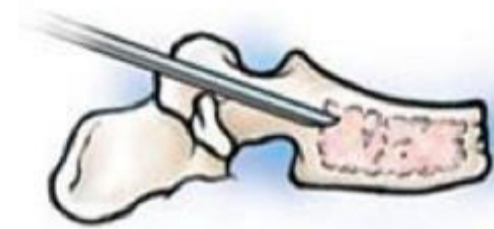


VERTEBROPLASTY IS A DIFFERENT PROCEDURE TO BALLOON KYPHOPLASTY

Cement is also injected into the vertebral body without the use of a balloon.



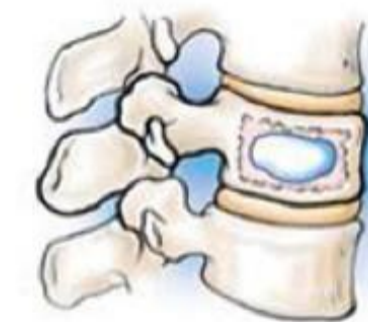
Problem:
Vertebral Compression
Fractures causing pain
and spine deformity.



Initial Entry:
A biopsy needle is
guided into the fractured
vertebra through a small
incision in the skin.



Stabilization: Acrylic
bone cement is
injected into the
vertebra, filling up
the vertebral body.



Post-op:
Vertebra with hardened
cement, vertebral
structure is stabilized
but not reduced.

VERTEBROPLASTY

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Kyphon™ Cement Delivery System (CDS) with
Kyphon V Premium Vertebroplasty System
allows you to:

- **Minimize Radiation Exposure¹⁸**
by standing up to 1.2 meters away from the radiation source which has been measured to reduce radiation exposure by 80%
- **Stop Cement Flow Instantly¹⁹**
by pushing the Quick Release button to minimize the potential for cement extravasation

MORTALITY RISK

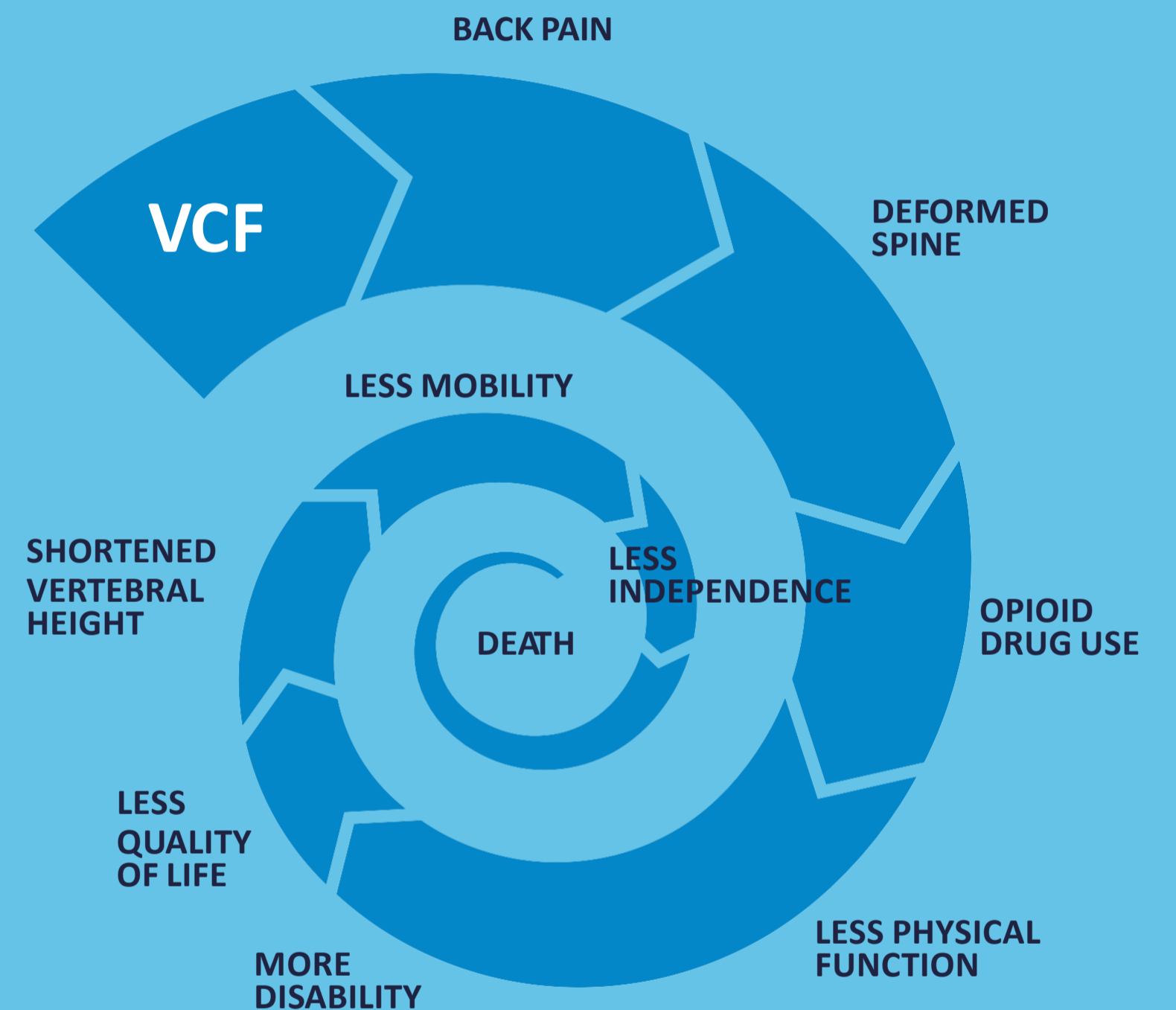
DOWNWARD SPIRAL OF COMPLICATIONS

AVOID THE RISKS

Early diagnosis and treatment are important steps to avoid the downward spiral of complications associated with untreated VCF²⁰⁻²⁴.

Over time, this condition may squeeze your internal organs and cause:

- reduced activity and mobility²³⁻²⁴
- sleep disorders and reduction in appetite²³⁻²⁴
- feelings of isolation and sadness²³⁻²⁴
- greater risk of future fracture²³
- risk of death²⁰



People with spinal fractures are at increased risk of complications and death compared with people who don't have spinal fractures²⁵.

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MORTALITY RISK

43% LOWER MORTALITY RISK FOR BKP/VP PATIENTS COMPARED TO NSM PATIENTS

Mortality risk evidence for vertebral compression fracture (VCF) patients treated with surgical (BKP or VP) vs. non-surgical management (NSM).



4 studies²⁶⁻²⁹



1,038,956 patients
(Edidin et al, 2015)



Up to 5 years
of MEDPAR data

KEY FINDING

Up to 43% lower mortality risk for BKP/VP patients vs. NSM patients, up to 5 years



1 study³⁰



126,392 patients
(McCullough et al, 2013³⁰)



1 year
of MEDPAR data

KEY FINDING

No difference in mortality risk between surgical and non-surgical patients

VCF PATIENTS AT HIGHER RISK

Patients with VCF have a higher mortality risk than non-VCF patients³¹.

And survival rates decline after VCF^{31*}.

Years after VCF	Decline in survival rate
3	53.9%
5	30.9%
7	10.5%

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MORTALITY RISK

Patients treated with balloon kyphoplasty (BKP)/ Vertebroplasty (VP) had up to 43% lower mortality risk, up to 5 years, than patients treated with non-surgical management (NSM), in several large studies²⁶⁻²⁹. One study showed no difference³⁰.

SIGNIFICANTLY LOWER MORTALITY RISK

**Edidin et al.
(JBMR 2011)**

N=858,978

BKP: 44% lower mortality risk than NSM
(AHR = 0.56, 95% CI 0.55 – 0.57)

VP: 24% lower mortality risk than NSM

(4 years)+

VP = vertebroplasty

BKP = balloon kyphoplasty

BKP(n=119,253)/VP(n=63,693)/NSM(n=676,032)

**Chen et al.
(JBJS 2013)**

N=68,752

BKP: 32.3% lower mortality risk than NSM
(AHR = 0.68, 95% CI 0.66 – 0.70)

VP: 15.5% lower mortality risk than NSM

(3 years)+

BKP(n=22,817)/VP(n=7,686)/NSM(n=38,249)

**Lange et al.
(Spine 2014)**

N=3,607

VP/ BKP: 43% lower mortality risk than NSM
(AHR = 0.57; 95% CI 0.48 – 0.70)

(5 years)++

BKP (n=441)/VP(n=157)/NSM(n=3,000)

**Edidin et al.
(Spine 2015)**

N=1,038,956

NSM: 55% higher mortality risk than BKP
(AHR = 1.55, 95% CI 1.53 – 1.56)

25% higher mortality risk than VP

After propensity matching, the Kaplan-Meier risk of mortality at 4 years was still found to be greater for the nonoperated cohort.

(AHR 1.62; 95% CI: 1.60-1.64)

(4 years)+

BKP (n=141,343)/VP(n=75,364)/NSM(n=822,249)

NO DIFFERENCE IN MORTALITY RISK

**McCullough et al.
(JAMA 2013)**

N = 126,392

BKP/VP: Significantly lower mortality risk than NSM

(AHR = 0.83; 95% CI: 0.75 – 0.92)

After propensity score matching to better account for selection bias, 1 year mortality was not significantly different between the groups (5.2% vs. 6.7%)

(HR 0.92; 95% CI: 0.81-1.04 (p=0.18))

(1 year)+

Vertebral Augmentation (n=10,541)/NSM(n=115,851)

+Adjusted mortality risk (p<0.001)/AHR= adjusted hazard ratio

+Retrospective database review of claims data that evaluated the mortality risk for patients with VCFs undergoing different treatment modalities

++Observational study of claims data that examined the survival of patients treated with BKP/ VP vs. NSM with a follow-up time of up to 5 years



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THE SAVINGS OF TREATING A VCF WITH BKP

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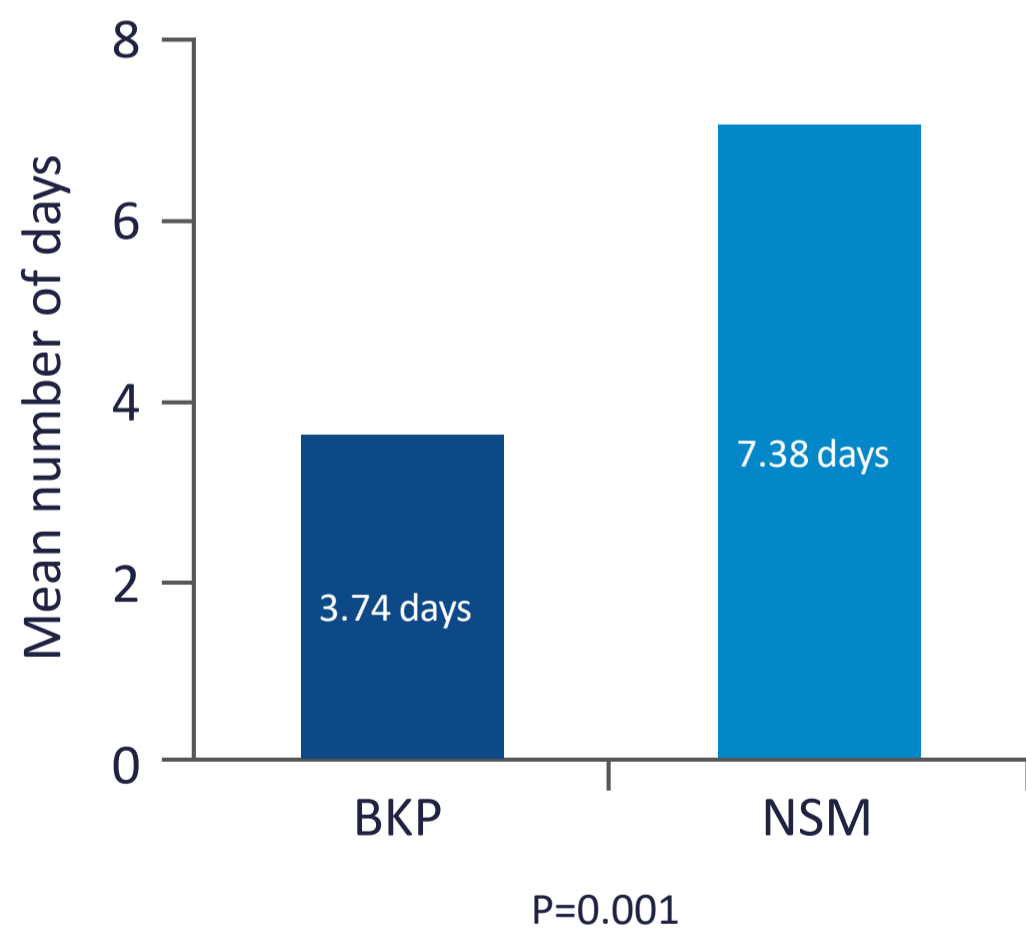
ECONOMIC VALUE

REFERENCES

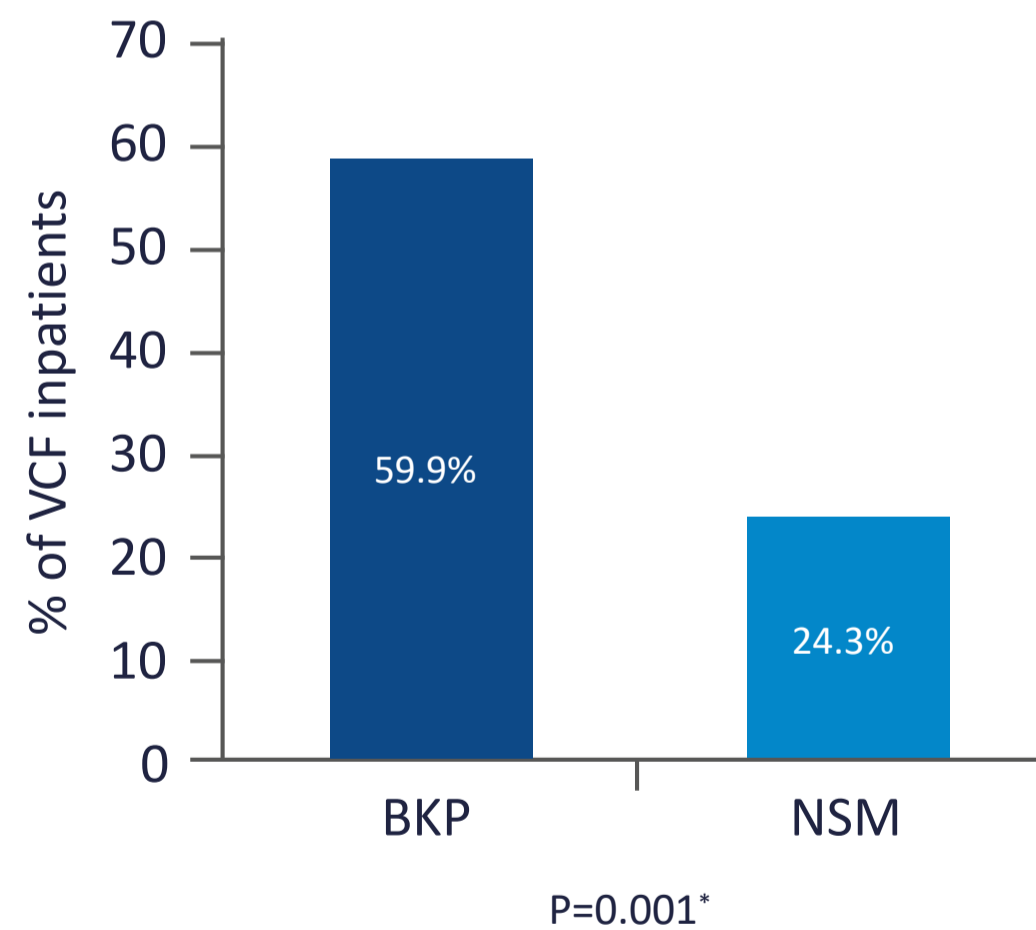


In a retrospective review of 68,752 patients³², compared with non-surgical management (NSM), balloon kyphoplasty (BKP) demonstrated:

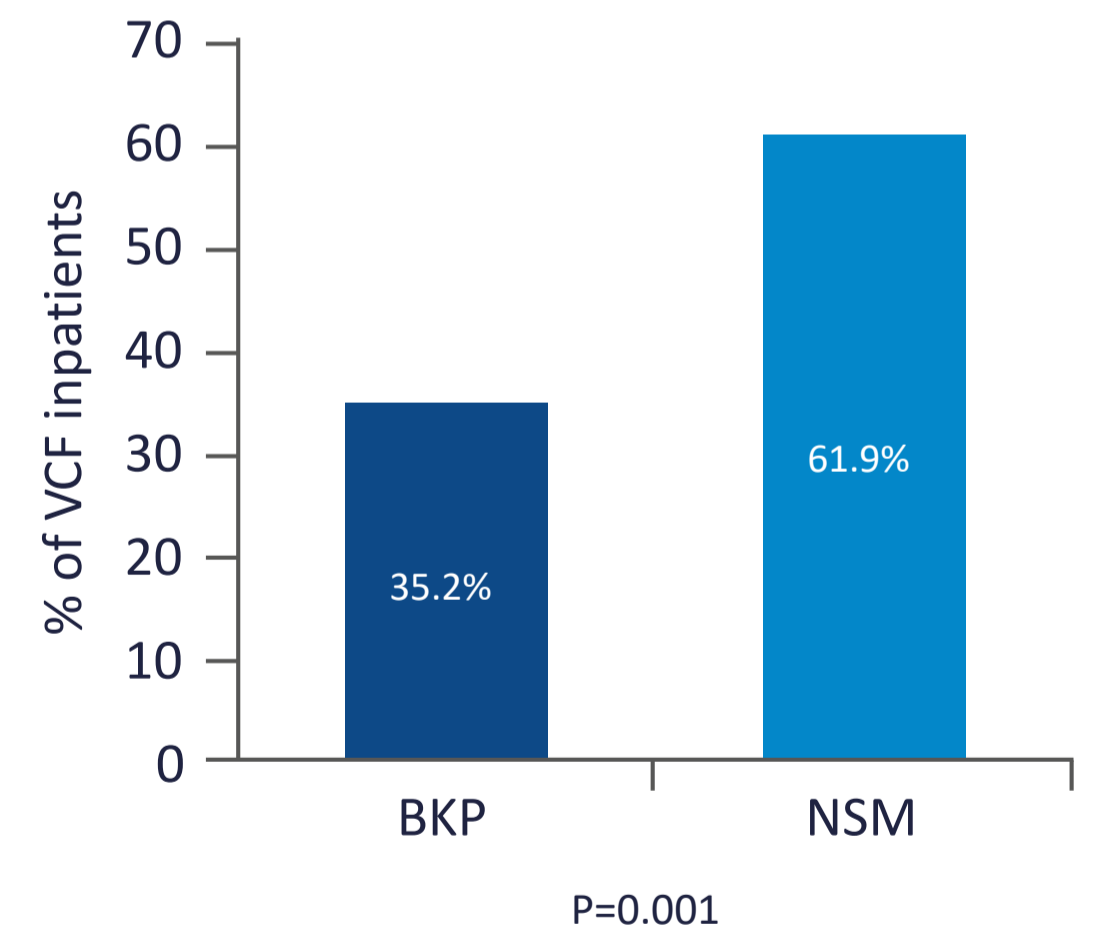
SIGNIFICANTLY SHORTER
LENGTH OF STAY



SIGNIFICANTLY GREATER
LIKELIHOOD OF ROUTINE DISCHARGES TO HOME



SIGNIFICANTLY LOWER
READMISSION RATE (WITHIN 30 DAYS)



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