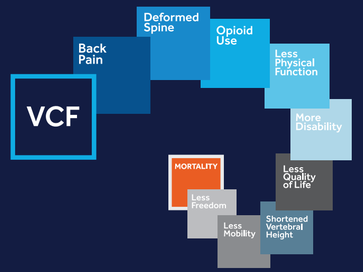
DOWNWARD SPIRAL

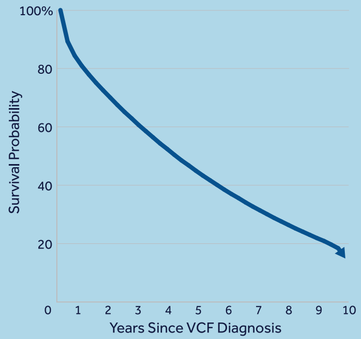
Vertebral compression fractures (VCFs) can result in a downward spiral of complications.[1-3]

VCFs pose significant burden for patients[4] and for healthcare systems.[5]



85% MORTALITY RISK[6*]

What does this mean for your patients diagnosed with a vertebral compression fracture?



Statistically significant

4% HIGHER MORTALITY RISK in 2010-2014

compared to 2005-2009[6**]

Medicare patients diagnosed with a vertebral compression fracture (VCF) were studied retrospectively from 2005 to 2014. The large (N = 2,077,944) cohort study found the risk of mortality for a VCF patient was 85.1% at 10 years.*

Vertebral augmentation patients comprised 20% of the VCF population in 2005, peaked at 24% in 2007–2008, and declined to 14% in 2014.

* At 10 years. All cohorts of VCF-diagnosed patients, propensity adjusted (95% CI, 84.7%-85.5%). $P < 0.001$.
** Propensity adjusted : 95% CI: 3%-4%; $P < 0.001$.

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Brief Statement
See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com

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Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

UNDERSTAND VCF MORTALITY RISK

Patients with vertebral compression fractures face steep mortality risk

REVIEW
THE EVIDENCE

Patients diagnosed with VCF deserve to understand the available evidence and know their treatment options.

Several recent, large clinical studies followed for at least 12 months after VCF have concluded that mortality rates following VCFs are significantly higher for patients treated conservatively versus VP or BKP, while other studies have concluded no difference.[5-10]

For more information, visit medtronic.com/bkpmortality

2+ Million
patients analyzed[6]

Majority of studies show there is

HIGHER MORTALITY RISK
for patients treated with NSM compared to BKP and VP[5-9]

At one year follow up[6]

↑ 55%
with NSM vs. BKP[6]

↑ 30%
with NSM vs. VP[6]

At up to 10 years follow up[6]

↑ 24%
with NSM vs. BKP[6]

↑ 8%
higher risk with NSM vs. VP[6]

One study showed no difference at 1 year follow-up.[10]

Significantly higher mortality risk for patients treated with NSM vs. BKP/VP

	YES / NO	N =	YEARS FOLLOW-UP
Ong KL, et al.* *(Osteo Int 2017)[6]*	✓	**2,077,944**	10**
Lange A, et al.* *(Spine 2014)[7]*	✓	**3,607**	5†
Edidin AA, et al.* *(Spine 2015)[8]*	✓	**1,038,956**	4**
Edidin AA, et al.* *(JBMR 2011)[9]*	✓	**858,978**	4**
Chen AT, et al.* *(JBJS 2013)[5]*	✓	**68,752**	3**
McCullough BJ, et al. *(JAMA 2013)[10]*	X	**126,392**	1**

LIMITATIONS
All studies presented:
1. Are retrospective database analyses and are prone to selection bias
2. Have variables that are not captured in the database, which may explain mortality effects
3. Have study designs that cannot demonstrate causality of treatment received with mortality outcomes
4. Indicate, to some extent, that BKP and VP subjects have better "baseline" health, which may at least partially explain the mortality benefit

AHR = adjusted hazard ratio
* Adjusted mortality risk ($p < 0.001$)
** Retrospective database review of claims data evaluating mortality risk for VCF patients given different treatment options
† Observational study of claims data examining survival of patients treated with BKP or VP vs. NSM for up to 5 years

For more information, visit
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- BKP (n = 261,756)/VP (n = 117,232)/NSM (n = 1,698,956)
- NSM: 55% and 24% higher mortality risk at 1 year and 10 years vs. BKP (Propensity adjusted: 95% CI: 23-24%; $p < 0.001$)
- NSM: 30% and 8% higher mortality risk at 1 year and 10 years than VP (Propensity adjusted: 95% CI: 8%-9%; $p < 0.001$)

- BKP (n = 157)/VP (n = 441)/NSM (n = 3,009)
- VP/BKP: 43% lower mortality risk vs. NSM
  (AHR = 0.57; 95% CI: 0.48–0.70)

- BKP (n = 141,343)/VP (n = 75,364)/NSM (n = 822,249)
- NSM: 55% higher mortality risk vs. BKP *(AHR = 1.55; 95% CI: 1.53–1.56)* and 25% higher mortality risk vs. VP.
- After propensity matching, the Kaplan-Meier risk of mortality at 4 years was still found to be greater for the non-operated cohort.
  (AHR = 1.62; 95% CI: 1.60–1.64)

- BKP (n = 119,253)/VP (n = 63,693)/ NSM (n = 676,032)
- BKP: 44% lower mortality risk vs. NSM
  (AHR = 0.56, 95% CI 0.55–0.57)
- VP: 24% lower mortality risk vs. NSM

- BKP (n = 22,817)/VP (n = 7,686)/NSM (n = 38,249)
- BKP: 32.3% lower mortality risk vs. NSM
  (AHR = 0.68, 95% CI 0.66–0.70)
- VP: 15.5% lower mortality risk vs. NSM

- Vertebral Augmentation (n = 10,541)/NSM (n = 115,851)
- BKP/VP: Significantly lower mortality risk vs. 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])

BALLOON KYPHOPLASTY INDICATION AND RISK STATEMENT

Kyphon™ Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

The overall complication rate with the procedure has been demonstrated to be low. Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, cardiac embolism.

For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.