

SAFEHIP®

THE HIP PROTECTOR



TYTEX®

MAKING HEALTHCARE MORE HUMAN

Agenda

1. Hip fracture

1.1 Facts about hip fractures

1.2 Consequences of hip fractures

2. Why hip protectors?

3. Cost-effectiveness

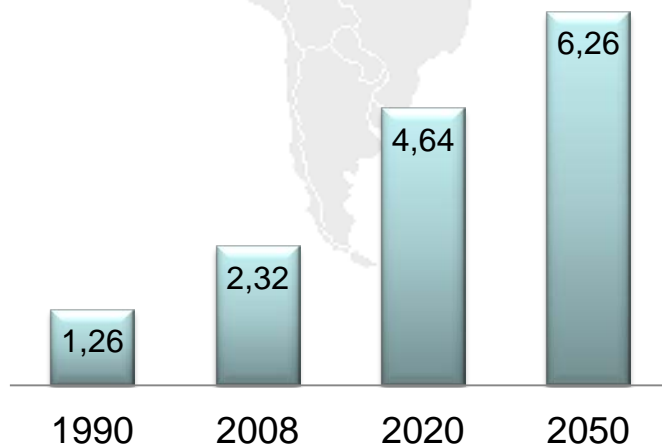
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1.1 Facts about hip fractures

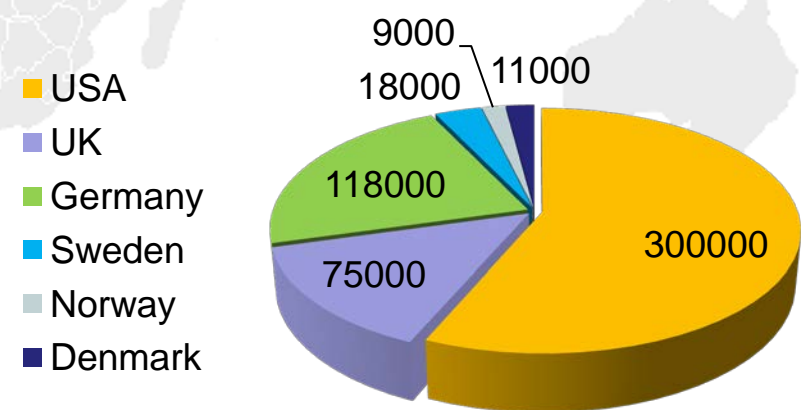
How common are hip fractures?

- Millions of people fracture a hip every year worldwide
- As the population ages, fall and hip fractures are expected to escalate
- The global number of hip fractures is expected to exceed 6.26 million before 2050
- 90 percent of all hip fractures are caused by a fall

Hip fractures worldwide

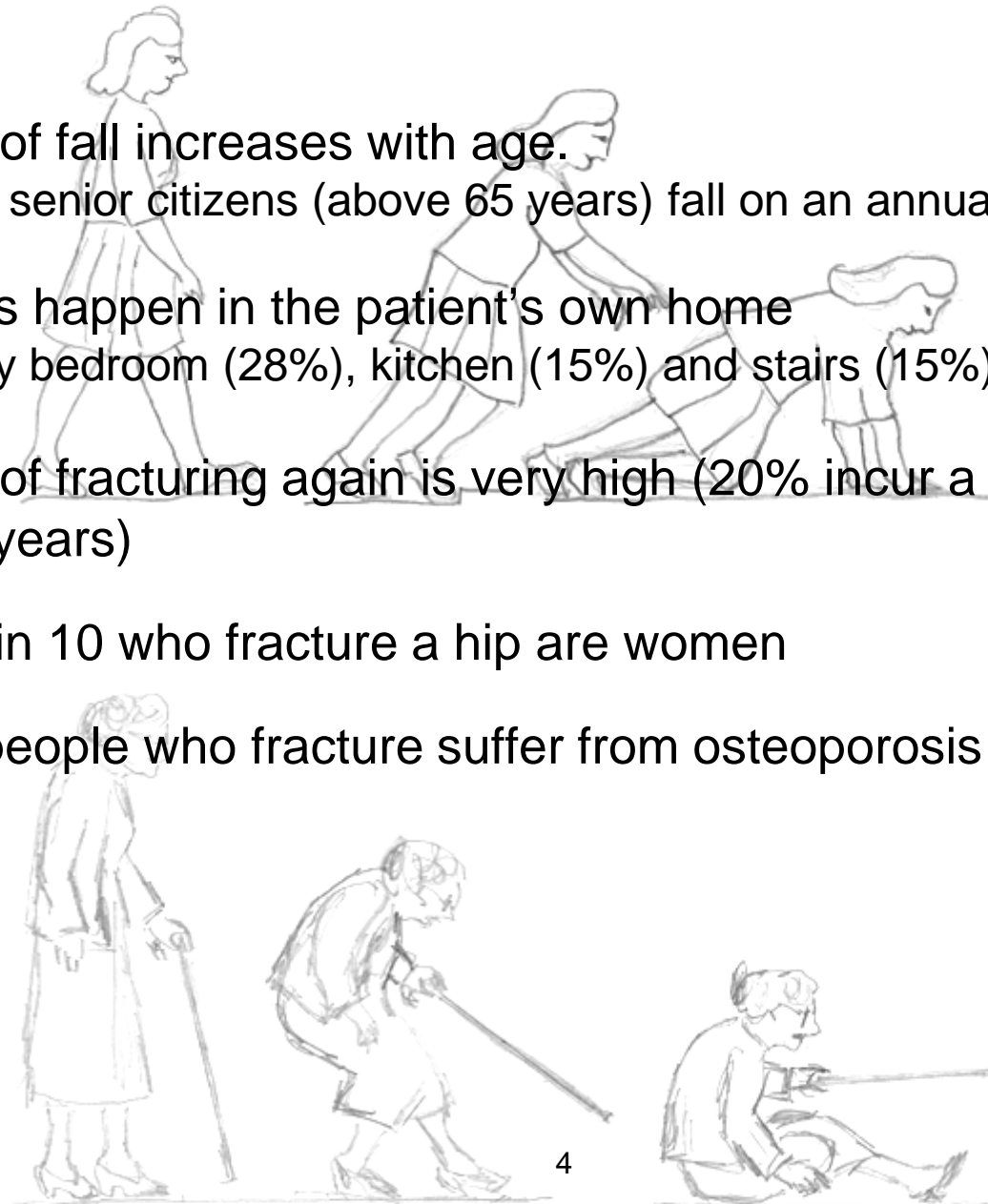


Hip fracture incidents 2011



1.1 Facts about hip fractures

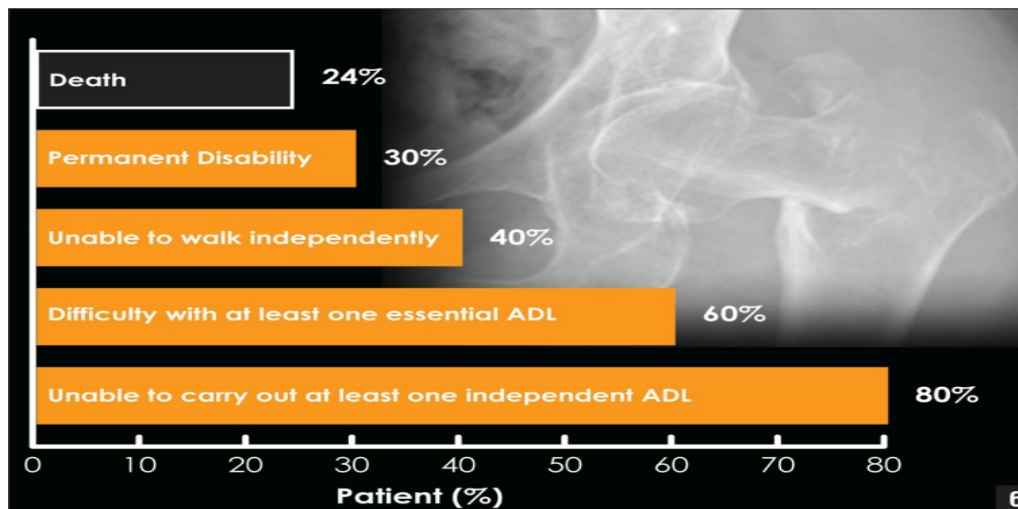
- The risk of fall increases with age.
 - 1 in 3 senior citizens (above 65 years) fall on an annual basis³
- Most falls happen in the patient's own home
 - mainly bedroom (28%), kitchen (15%) and stairs (15%)
- The risk of fracturing again is very high (20% incur a new hip fracture within 5 years)
- About 8 in 10 who fracture a hip are women
- 85% of people who fracture suffer from osteoporosis



1.2 Personal consequences of hip fractures

A replacement or repair of a hip is not a miracle cure

- Hip injuries require painful and lengthy treatments
- 78% of hip fracture patients come from their own home – but only 46% are discharged to their own home – 10% never leave the hospital⁹
- 50% will never regain previous independence⁶
- 20% of all hip fracture patients will die of their hip fracture within 12 months
- 1% within 60 days⁵



ADL: Activities of Daily Living

1.2 Personal consequences of hip fractures

Lost independence

- A hip fracture is not just a broken bone in isolation as a broken finger. When you break a weight bearing bone as the hip you are immediately immobilized. You are not able to walk or get up by yourself.
- The recovery period increases with age and for many elder people a hip fracture is the beginning of a steady decline in the person's ability to function.
- You become highly dependent of other's help. Only around half of the elder living at home can remain at home after a hip fracture



1.2 Personal consequences of hip fractures

Lack of confidence

- Can you imagine the fear of falling after having been through a painful hip fracture, a huge operation and a lengthy recovery period?.
- Often the patient lose confidence and is afraid of falling again.
- The lack of confidence and fear of falling often have a negative effect on the person's mobility and the risk of falling might increase.



1.2 Personal consequences of hip fractures



Social isolation

- Up to 80% never regain previous mobility
- Visiting the neighbour might suddenly seem like a mission.
- The reduced mobility, lost Independence and fear of falling often result in social isolation as it becomes difficult to leave home

Agenda

1. Hip fracture

2. Why hip protectors?

3. Cost-effectiveness

2.1 Why hip protectors?

2.2 Evidence of effectiveness

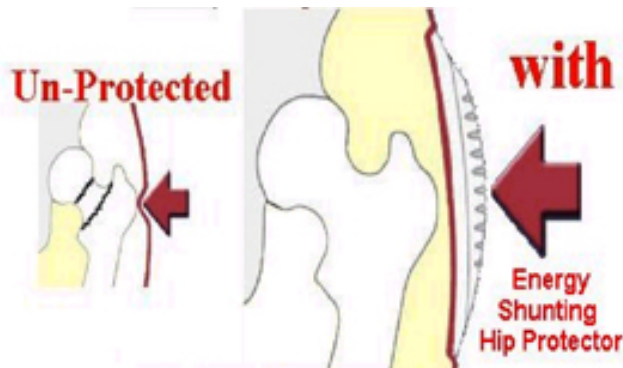
2.3 SAFEHIP

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2.1 Why hip protectors?

Prevention is better than cure!

- **Medical treatment.** Medication may help strengthen the bone density to avoid the bone from breaking that easily
- **Prevent the fall** as about 90% of all hip fractures occur due to fall. A number of fall preventing programmes have shown good results.
- **Prevent the impact** on the femur. If you cannot prevent the fall, you may prevent the impact on the femur with a hip protector, thereby minimizing the consequence of the fall.



2.1 Why hip protectors?

What is a hip protector?

- Hip protectors are not a fall prevention initiative. They have no influence on the frequency of falls, but they have an influence on the consequences of the fall

A SAFEHIP® hip protector consists of a pair of shields and a set of trousers which ensure that the shields are placed correctly.

The SAFEHIP® hip protectors are based on impact energy dispersion and impact energy absorption.

In the event of a fall on the hip, the SAFEHIP® hip protector disperses the energy from the impact away from the greater trochanter (hip bone). This means that the energy from the fall is absorbed by the soft tissue and the muscles around the femoral neck, thereby reducing the risk of a hip fracture

2.1 Why hip protectors?

- Hip protectors should be seen as a product that contributes to a person's safety on the same level as seat belts, lifejackets, helmets etc.
- It reduces the risk of serious injuries, saves money and improves quality of life (person becomes more active, less afraid of falling etc.)
- As with most other safety products SAFEHIP® hip protectors cannot prevent all hip fractures, but the effect of them has been clinically proven and they may reduce the risk of fracturing a hip by more than 2/3.

Aging is a Contact Sport

Does your team have the right gear?



2.1 Why hip protectors?

- The first hip protector was launched in 1993
- SAFEHIP® was the first hip protector on the market
 - a set of hard shields to absorb the effect from the fall
 - a pair of briefs in order to place the shields at exactly the right place over the hip bone
- The protecting shields have been under constant development since:
 - To gain better results in the bio-mechanical and clinical tests
 - To meet the requirements of better comfort
 - SAFEHIP® is now at 5th generation



2.2 Evidence of effectiveness

Hip protectors have been proven effective

There are many ways to test the effectiveness of hip protectors

- Many theoretical tests for measuring the effectiveness have emerged over time and can be used for the initial testing

Different results have occurred, due to:

- Different test methods
- Fall test difficult to perform
- Lack of compliance

For the true effectiveness of a hip protector a clinical trial is needed.

- A test with the specific protector using real people
- SAFEHIP® is the most clinical tested hip protector

2.2 Evidence of effectiveness

Hip protectors only work when they are worn!

The importance of compliance

- There has been found no clinically relevant difference in the acceptance and probability of continued use between soft and hard-shielded hip protectors in nursing homes
- Studies show that significantly more users of soft hip protectors used the protectors 24 hours a day because they were more comfortable

Compliance can be improved by:

- Education of users, relatives and caregivers in the use and importance of wearing the hip protectors.
- Motivation and proper instruction of users in the use and benefits of hip protectors
- Caregivers monitoring the use of hip protectors, making sure that the hip protectors are worn.

2.2 Evidence of effectiveness

Canada 2008
Women in long term care
Reduction: 77%

USA 2000
1801 ambulatory
frail elderly adults
1409 women, 392 men
Reduction 60%

Norway 2004
Nursing homes
705 residents
Reduction 69%

Norway 2008
1236 resident
18 nursing homes
Reduction 64%

Denmark 1999,
Nursing home:1000 men,1000 women
Reduction: Men 71%, women 56%

Denmark 2010:
Nursing home
Reduction:68.6 %

Germany 2005
49 nursing homes
942 residents
Reduction 40%

Japan 2009
76 nursing homes
672 ambulatory
elderly women
Reduction: 63%

The reduction rate is "only" around 2/3 due to lack of compliance,
spontaneous hip fractures and fractures not caused by a fall

2.3 SAFEHIP®

The story behind SAFEHIP®

The shields

- The first protector: The hard shield
 - Tytex was the first company to develop a hip protector back in 1993 where the hard shield was presented
 - It was developed in co-operation with the Danish orthopedic surgeon Jes Bruun Lauritsen
 - The hard shield has been subject to most trials
- The soft foam shield: The first horseshoe
 - The first version of the light weight soft foam shield was developed in 2006
 - In the process of development Tytex received external support from experts (Professor Steve Robinovitch, Director NordiCare Helena Peters and orthopedic surgeon Jes Bruun Lauritsen)
- The AirX™ shield: Textile based horseshoe
 - SAFEHIP® AirX™ was developed in 2007 and introduced worldwide in the spring of 2008 with great success



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2.3 SAFEHIP®

Classic



AirX



Active



2.3 SAFEHIP®

General features for all SAFEHIP products



Oeko-tex tested

Tested for harmful substances according to Oeko-Tex standard 100

- No harmful substances in the selected materials
- Reduces the risk of skin irritation and allergy
- Of particular importance in the healthcare sector

**LATEX
FREE ZONE**

Latex Free

Latex free products for the sake of patient and caregiver.

- Some people have a serious latex allergy, and exposure to latex products may cause an anaphylactic shock
- Of particular importance in the healthcare sector



CE marked

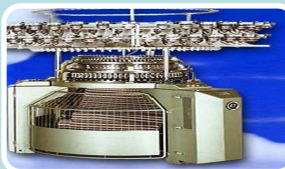
Products meet EU safety, health or environmental requirements

- key indicator of a product's compliance with EU legislation
- enables the free movement of products within the European market.



Horseshoe shaped shields

Absorbs and disperse the force away from the critical area



Seamless fixation pants

**No irritating labels or seams on the skin
(SAFEHIP® Active not included)**

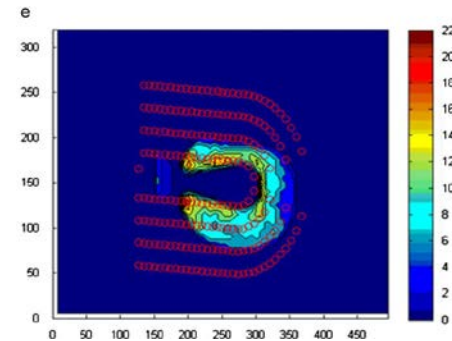
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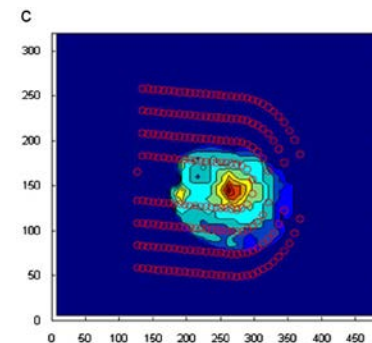
2.3 SAFEHIP®

The horseshoe design

- The horseshoe design both absorbs and disperses the force away from the critical area
- Standard hip protectors merely absorb the force from a fall
- The horseshoe is a Tytex patent
- Published articles with tests performed with a horseshoe against a continuous protector have proven that the horseshoe will provide better protection of the critical area¹⁰



Horseshoe protector



Standard protector



An unprotected sideways fall onto the hip is the most common cause of hip fractures

2.3 SAFEHIP®

The pant design

- **Seamless design**
 - All AirX and Classic pants are light weight and knitted in one process making them seamless
 - No irritating labels or seams on the skin as care instruction and size are knitted in
- **Fixation pant**
 - Ensures the shields are held in place
 - All pants are fixation pants that can hold a continence pad in place if needed.



Seamless technology



SAFEHIP® Classic

- For hospitals, nursing homes or at home
- For people requiring intensive nursing care
- Horseshoe shaped PE-foam shield (polyethylene)
- Optimal conformability
 - Seamless pant
 - Easy fitting
 - Pants are designed to act like fixation pants to hold an incontinence pad in place securely
- High biomechanical performance
- Discrete and comfortable to wear
- Most clinically tested shield
- Washable at 60°C
- Tumble-dryer safe



2.3 SAFEHIP®



SAFEHIP® Classic

- Two models
 - Unisex
 - Fixation pants. Can fixate a continence pad for light to medium incontinence - if needed.
 - Designed to be worn underneath your normal clothes and over your underwear
 - Open
 - For high level of incontinence
 - Designed to be worn underneath your underwear
- Multi pack with removable shield



Washing	Styles	Shield	Composition	Color	Sizes
140°F/60°C	Unisex, Open	Soft foam horseshoe	71% cotton, 25% polyester, 4% elastane	White	XS – S – M – L – XL - XXL



SAFEHIP® AirX™

- For hospitals, nursing homes or at home
- For people requiring intensive nursing care
- Horseshoe shaped AirX™ shield (soft spacer fabric)
- AirX™ is a material substitution/improvement of the existing SAFEHIP® classic shield. The clinical test results related to SAFEHIP® are regarded as applicable
- Improved biomechanical performance
- More flexible (more comfort)
- High breathability* (100% textile)
- High compliance
- Washable at high temperatures, 95°C, pant & shield together. Ensures the shield always is placed correctly
- Tumble-dryer safe at highest temperature



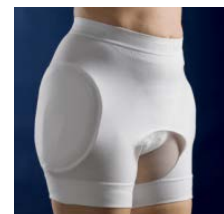
*According to a recognized test institute: "SAFEHIP® AirX™ has a significantly better thermo physiological behavior than competitive products and result to a better wear comfort." (EMPA test report no 448819, March 2008)²⁴

2.3 SAFEHIP®



SAFEHIP® AirX™

- Optimal conformability
 - Seamless pant
 - Easy fitting
 - Pants are designed to act like fixation pants to hold an incontinence pad in place securely
 - Breathable AirX™ textile based horseshoe shield
- 4 Models:
 - Unisex, female, male
 - Fixation pants. Can fixate a continence pad for light to medium incontinence - if needed.
 - Designed to be worn underneath you normal clothes and over your underwear
 - Female: with knitted flowers. Male: with fly
 - Open
 - For high incontinence
 - Design to be worn underneath your underwear
- CE-marked medical device, Latex Free, Oeko-tex certified

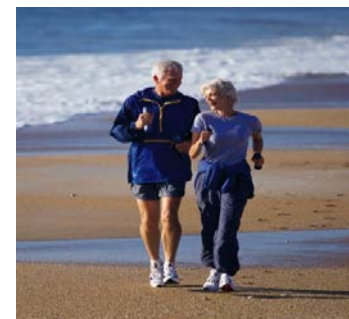


Washing	Styles	Shield	Composition	Color	Sizes
200°F/95°C	Unisex, Male, Female, Open	AirX™ horseshoe	36% polyamide, 58% cotton, 6% elastane	White	XS – S – M – L – XL - XXL



SAFEHIP® Active

- For use in rehabilitation and training centres, and for use at home
- Easy to put on and take off for both the user and care givers
- To be used over normal clothing
- Horseshoe shaped PE foam shield (like Classic)
- CE-marked medical device, Latex Free, Oeko-tex certified




Washing	Styles	Shield	Composition	Color	Sizes
Hand wash	Unisex	Soft foam horseshoe	85% polyester, 15% elastane	Black	S – M – L – XL - XXL

2.3 SAFEHIP®

Classic	Main Use	Washing	Styles	Shield	Composition	Color	Sizes
	Hospitals, nursing homes or at home	140°F/ 60°C	Unisex, Open	Soft foam horseshoe	71% cotton, 25% polyester, 4% elastane	White	XS – S – M – L – XL – XXL

Air X	Use	Washing	Styles	Shield	Composition	Color	Sizes
	Hospitals, nursing homes or at home	200°F/ 95°C	Unisex, Male, Female, Open	AirX™ horseshoe	36% polyamide, 58% cotton, 6% elastane	White	XS – S – M – L – XL – XXL

Active	Use	Washing	Styles	Shield	Composition	Color	Sizes
	rehabilitation and training centres, and home use	Hand wash	Unisex	Soft foam horseshoe	85% polyester, 15% elastane	Black	S – M – L – XL – XXL

2.3 SAFEHIP®

Why SAFEHIP®?

- SAFEHIP® reduces the risk of hip fractures
- SAFEHIP® is the most clinically proven hip protector in the world
- SAFEHIP® was the first hip protector in the world and is constantly being developed to improve biomechanical effect and comfort
- SAFEHIP® is the only hip protector in the world using the patented horseshoe shaped protector that brings outstanding force reduction capabilities
- SAFEHIP® AirX is the only 100% breathable textile based hip protector in the world
- SAFEHIP® AirX can be washed at 95 degrees – pants and shields together (ensures that the shield always is placed correctly)

Agenda

1. Hip fracture
2. Why hip protector?
3. Cost-effectiveness

3.1 Cost-effectiveness

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3.1 Cost-effectiveness

Hip fractures not only have a major impact on a personal level - they also constitute a major cost on the national health systems

- **Hip fractures count for the most hospital beds**
 - About 300,000 Americans are hospitalized for a hip fracture every year
- **As the population ages, the cost of hip fractures are expected to escalate**
 - Measures to reduce the incidence of fractures will generate significant savings for all health care systems
- **Hip protectors are found cost-effective in high-risk populations**
- **The cost-effectiveness depends on many parameters:**
 - Potential risk: gender, age, race
 - Cost and number of hip protectors needed per person
 - Cost of education and extra time of health personal for dressing
 - Etc.

3.1 Cost-effectiveness

Estimated savings

- **In the UK**

- Each hip fracture stands between £25,000 and £32,000 per person
 - corresponds to the price of 750 hip protectors
- The number of hip fractures each year in the UK is over 60,000 and the cost to the NHS and social care service is at least £1.73 Billion per year⁸. 2% of the national budget.

- **In the US**

- Lifetime savings to Medicare per high risk resident US\$223
- Medicare could save US\$136 million in the first year of a hip protector reimbursement programme
- US\$283 million in discounted savings over this group's remaining lifetime

- **In Denmark**

- The Danish National Board of Health estimated in a national Danish newspaper (JP) in 2010 that there would be a net saving of 15 – 20 million DKK if hip protectors were used in all nursing homes in Denmark⁷



3.1 Cost-effectiveness

The use of hip protectors is an important and cost-effective strategy in preventing hip fractures in high-risk populations.

Promotion of hip protectors at an institutional, rather than at the individual level may dramatically improve the compliance in nursing homes.

Current reimbursement policies e.g. in the U.S. place the economic burden of providing hip protectors on nursing facilities which may not reap the financial benefit associated with the fracture prevention¹⁴.

Sources

1. Gullberg B, Johnell O, Kanis J (1997), Worldwide projections for hip fracture, *Osteoporosis Int* 7:407-413
2. Singh, Sun and Anis, 2004. Cost-effectiveness analysis suggests that hip protectors could save money while preventing hip fractures and improving quality of life in nursing home residents. *Journal of Rheumatol* 2004;31:1607–13)
3. Brot C, Skjoeth TV, Nielsen K, (2006), *Faldpatienter i den kliniske hverdag - rådgivning fra Sundhedsstyrelsen*, Sundhedsstyrelsen (The Danish National Board of Health)
4. Lauritzen JB, Backe H, Søgaard R, Sundhedsstyrelsen, *Monitorering & Medicinsk Teknologivurdering*, (2010), *Hoftebeskyttere til forebyggelse af hoftebrud - en kommenteret udenlandsk medicinsk teknologivurdering*, Sundhedsstyrelsen (The Danish National Board of Health)
5. Forsen L et al., (1999), *Survival after Hip Fracture: Short- and Long-Term Excess Mortality According to Age and Gender*, *Osteoporosis International*
6. Salkeld et al, *J Gerontology*, 2000; 55, 299.
7. Currie et al, *The National Hip Fracture Database National Report 2010*; NHS 2010
8. Choi et al, *The effect of positioning on the biomechanical performance of soft shell hip protectors*, *Journal of Biomechanics*, doi:10.1016/j.jbiomech.2009.11.023
9. Bentzen et al, *Risk of hip fractures in soft protected, hard protected, and unprotected falls*, *Inj Prev*. 2008 Oct;14(5):306-10
10. Forsén et al, *Risk of hip fracture in protected and unprotected falls in nursing homes in Norway*, *Injury Prevention* 2004;10:16–20. doi: 10.1136/ip.2003.003889
11. Koike et al, *External hip protectors are effective for the elderly with higher-than-average risk*, *Osteoporosis Int* (2009) 20:1613–1620'