How safe are hip protectors?

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Summary

Hip protectors are becoming more common in use in the management of the elderly at risk of fracturing their hip following a fall onto a hard surface. There are many designs appearing which have soft and/or hard elements secured in a garment that acts as the delivery system. Nursing staff have very few guidelines as to the most appropriate hip protector that is suitable for their patients. This article highlights the different designs available, the compliance issues, the mechanical performance of the different designs, tissue viability issues that nurses should be aware of, and questions and information nursing staff should consider in conducting a risk assessment and making an informed choice of the most suitable hip protector.

Introduction

Falls resulting in fracture of the hip in elderly people are a major health problem worldwide. These fractures can result in high risk of long term care requirement, morbidity and disability, and an increased risk of premature death [Keene et al, 1993]. It has been forecast that as the population ages, the number of hip fractures occurring throughout the world each year will rise from 1.66 million in 1990, to 6.26 million by the year 2050 [Cooper et al, 1992].

The prevailing view was that most hip fractures resulted from age-related bone loss or osteoporosis. It was thought that improving bone mass and density with exercise, calcium, and oestrogens, would reduce the risk of fracture of the hip and other bones due to falls. Whilst this view is not wrong, more recent studies seem to suggest that most hip fractures are due to a fall and a direct impact on the trochanteric area of the hip [Cummings and Nevitt, 1989]. About 25% of such falls cause hip fracture [Lauritzen et al. 1993]. Sufficient kinetic energy is produced in a fall from a standing position to fracture bone, even in young healthy persons [Robinovitch et al, 1991]. This falling mechanism and the energy absorption of the trochanteric soft tissue are the main determinants of hip fracture, rather than bone density loss [Lauritzen and Askegaard, 1992]. In addition to the suffering and loss of independence caused by hip fractures, is the high cost in monetary terms. In the United Kingdom the average cost of a hip fracture was estimated in 1994 to be £12,300, with over 60,000 hip fractures per year, the total annual cost then was approximately £742 million [Dept of Health, 1994]. With an increase in the elderly population, there is likely to be a proportional increase in the number of hip fractures and the associated mortality, morbidity and cost [Cummings et al, 1990, Runge, 1993]. The cost of a hip fracture in Belgium in 2001 was £6,000 for the initial hospital treatment, and £8,400 per year after discharge, or £4540 greater than the cost of caring for an age-related population [Haentjens et al, 2001]. In terms of opportunity costs in the UK, an additional total hip or knee replacement could be undertaken for every hip fracture avoided. When these costs are compared with the cost of hip protection, approximately £500 per person per year, external hip protection becomes a very good cost effective option as a method of preventing hip fractures in the elderly, from the points of view of both effectiveness and cost. Patient compliance is still a debated issue, but with a structured education programme and free provision of hip protectors to the elderly at risk, there are justified claims that hip fracture incidence can be reduced [Meyer et al, 2003]. Nursing staff need to ask the relevant questions pertaining to the correct choice of such a device to provide the best and safest protection for their patients. These should include: Comfort, fit, mechanical efficacy, positioning and coverage during movement, interface pressures, skin care over the greater trochanter, effect of washing, length of use and replacement/maintenance strategies, and price. Some of these questions can only be answered from laboratory studies, some from proper clinical trials and from the distributors. Currently, no Standards exist that hip protectors have to conform to on many of these issues and these are currently being addressed through a working committee of the

Surgical Dressings Manufacturing Association (SDMA). Four areas of Standards to cover all the above issues relating to the conditioning/washing, compliance and mechanical effectiveness are being compiled. This article describes the current laboratory studies that may answer the mechanical, positioning and tissue viability issues; and questions relating to these issues that nursing staff should consider when assessing whether a patient may be suitable for the provision of a hip protector.

Hip protector designs

The current designs of hip protectors either incorporate a thin preformed shell within a softer layered material [Lauritzen et al, 1993], an oval pad of curved dense foam, or a two part rigid oval polypropylene grill that is attached by sandwiching the pants type garment in between the shells (Fig 1). Except the last design, the pads are held in position by being incorporated into a garment that is supposed to keep the pad in the right location with respect to the greater trochanter that is just below the surface of the skin. Many patients do not continue wearing the garments because they are uncomfortable, and those that do; the pads may not be in the correct position when a patient falls.

Mechanical testing studies

To evaluate how safe these devices are at providing impact resistance during a fall, it is necessary to characterise the force shunting and energy absorption characteristics of hip protectors, and an impact testing rig was designed and constructed for this purpose. The forces and energies encountered during a fall are well documented from laboratory tests on cadavers and from analytical studies [Van der Kroonenberg et al, 1993, Robinovitch et al, 2000]. The most realistic rig used to evaluate hip protectors was developed by Mills [Mills, 1996], which comprised of a cylinder mounted above a load cell, covered with a "skin" of viscoelastic polymer rubber 20 mm thick. To simulate the force and energy encountered during a fall, it was estimated that either a peak force of 2.5 kN or an impact kinetic energy of 120J would result in a fracture [Parkkari, et al, 1994]. The striker mass to reproduce these values was 35Kg falling from a height of 0.35m. Kannus et al [Kannus et al, 1999] designed a pendulum that struck a vertically mounted surrogate pelvis and femur arrangement with peak contact forces up to 10.84kN, well above the lowest fracture force to cause an osteoporotic hip to break [Robinovitch et al, 1991]. After discussing the representative impact parameters to base a comparative study on (Prof J Lauritzen-personal communication, Nov 2002) an impact velocity of 3.16 m/sec and a peak force on the greater trochanter of 3.5 kN was simulated. A simple impact test rig was constructed that produced representative impact velocities and peak forces reported in the above quoted papers and identical impact tests were performed three times on three specimens of 6 commercially available designs which have been used clinically.

Tissue viability aspects

There have been no studies on the tissue viability issues of wearing hip protectors either in a garment or attached to the skin. Misplacement, and conformity with the skin could give rise to large obligue and shear forces and high interface pressures on the skin over the greater trochanter. This area is known to be susceptible to damage, especially in the frail elderly that may need hip protectors. A further study was undertaken to investigate the effect of shape and misplacement on the interface conditions under likely physiological loads over a model of the area of the greater trochanter, and to assess the protection to the soft tissue of various designs in use. This is an important factor to evaluate the "force shunting" effect of the different protectors that incorporate a hard shell. Shape data was obtained by outlining the surface profile in the sagittal and horizontal planes centred on the greater trochanter of twenty elderly women admitted for a fracture of the contralateral side. An average shape was established and compared with the horizontal section of four commercially produced hip protectors to ascertain the amount of shape conformity and contact with the surface of the skin around the greater trochanter . For some designs, the horizontal cross section of the shells may give rise to a small localised area of contact directly over the greater trochanter which negates the "force shunting" effect. The position of the greater trochanter relative to the skin was measured at various angles of hip flexion using a SafeHip garment with a hole in the centre of the pad. The effect of misplacement of the pads on the protective effect was evaluated which, when combined with the effect of movement of the greater trochanter during flexion of the hip, the periphery of the pad may become sited over the greater trochanter. In this situation, the load transfer occurs through he pad material thickness directly to the greater trochanter rather than through the shell shape (Fig 3). These conditions produce a poor impact resistance performance of the designs which incorporate a hard shell. A pressure mat was used to measure the extent, shape and values of the contact pressure of subjects lying on their side (Fig 4). The interface pressure pattern was circular, centred on the centre of the palpated greater trochanter. Interestingly, pressure sores that occur over the greater trochanter appear circular in shape (Fig 4). To more clearly obtain values of the interface pressure between pads and the skin over the greater trochanter, an Oxford Pressure Monitor was used with a single cell mounted over the greater trochanter to

ascertain the interface pressure whilst lying directly on the hip protector to simulate a sleeping position. The interface pressures ranged from 60 to 137 mm Hg in 4 commercial devices for a subject 65 Kg bodyweight lying with the garment on in a position likely to occur whilst sleeping. It is suggested that 60 mm Hg is the maximum interface pressure at the greater trochanter especially as this pressure is likely to lead to an unacceptable pressure-time regime that will lead to potential tissue damage [Reswick and Rogers, 1976]. Many patients are nursed on a turning regime if they are at risk of tissue damage if subjected to interface pressures above a certain value for long periods of time as a consequence of this pressure-time phenomena. Clearly, it would be costly and impractical to expect subjects who wear hip protectors to turn at night to avoid these damaging pressure-time regimes.

Risk assessment issues for nursing staff

Nursing staff should ascertain and include the following when planning or conducting a risk assessment of an individual patient indicated for potential use of a hip protector to reduce the risk of fracture of a hip from a fall:

Seek from the supplier/manufacturer:

- 1. Evidence of patient compliance of the device and in what groups/subject mix this evidence is based on. If medical claims are made for these devices, then there is a legal requirement under the Medical Devices Directives that these products must have a CE mark.
- 2. Contra indications/exclusion criteria for its use.
- 3. Evidence on the correct positioning of the pad in the delivery system on a patient of similar makeup to the patient being assessed (either published data or by demonstration on your patient or on a subject of similar anatomy) especially movement during hip flexion.
- 4. Any interface pressure data, any impact reduction and energy absorption data either by demonstration or reliable laboratory/clinical evidence, published or independent testing. (Be very wary of internal reports produced by the manufacturer that may not be controlled and not subject to peer review).
- 5. Any performance data for soiled/wet garments in particular an increase in any detrimental interface conditions that may compromise the local tissue viability especially directly over the greater trochanter.
- 6. Any maintenance schedule or monitoring system in place, such as visual inspection or otherwise, that the subject has fallen onto the device and possibly changed or compromised its mechanical efficacy, and what is the replacement policy for used/ damaged/soiled/wet devices/garments.
- 7. Compatibility or interference problems with incontinence aids or devices such as catheters, pads etc.
- 8. Interaction with clothing over the garment such as friction, static and with closure devices such as zips, buttons, Velcro etc.

Also one should consider incorporation into an existing risk assessment analysis system for pressure sores, patients that may not be suitable for wearing a hip protector because of the pressure relieving system the patient may be on (for instance, patients wearing a hard shell hip protector garment may have the shell impinging on the skin whilst seated in a custom-made wheelchair cushion that has been made without a hip protector in place).

Features of different designs of hip protectors

Table 1 lists the various features of different designs of hip protectors, highlighting the mechanical and clinical advantages and disadvantages for designs which utilise hard, soft and combinations of both as well as the concept of skin mounted devices. Nursing staff may find this table useful (which is not exhaustive as one may well add further aspects of the various designs not included) to compile further questions to ask the designers and distributors.

Conclusions

There is currently major confusions for nursing staff as to the decision whether a, and if so which, hip protector is appropriate to a particular patient. This article presents to the nursing staff information as to the various aspects one should consider in making those decisions. The features, mechanically and clinically, that various designs have are presented as well as suggested questions that nursing staff should ask of researchers, manufacturers and distributors. Clearly, there are some pads that are of concern for their impact characteristics and a committee has been formed comprising of research scientists, manufacturers and nursing staff to draw up protocols to standardise the testing of hip protectors. To be included in the standards on safety testing are the tissue viability issues, as misplacement and conformity with the skin could give rise to large obligue and shear forces, and high interface pressures on skin over the greater trochanter which is known to be susceptible to damage especially in the frail elderly that may need hip protectors. As a consequence, the shape of hip protectors and their design related to function needs to be addressed, and the standards produced on this aspect need to reflect these clinically important tissue viability aspects as well as effects of conditioning and the delivery systems for the protectors. Correctly positioned hip protectors need to be conforming with the skin around the greater trochanter, but many of the designs are sufficiently flat on highly curved areas around the lateral hip that direct contact with the greater trochanter is often made and the skin over the greater trochanter becomes highly compromised. Groups are developing soft hip protectors that may be mounted directly onto the skin which has many attractions from the clinical and compliance aspects, and these together with the current designs may offer a wider range of safe devices to reduce the increasing costly problem in terms of health and the limited financial resources to the NHS, of the elderly fracturing their hips.

Table 1		
Pad design	Advantages	Disadvantages
Hardshell, in garment. eg HIPS	Force shunting effective on non bony subjects. Garment appears to ensure correct positioning of the pads in use.	Very little energy absorption. Very little protection on bony subjects. Not obvious if shell broken in use and becomes non effective at force shunting. Very difficult to lie on during sleeping-too prominent and feels hard. If separate from garment, needs correct positioning to avoid edge covering the GT. Cosmetically, can appear prominent. Garment can be difficult to put on and off, especially for the disabled user, and is noticeable through clothes. Tissue viability problems if garment becomes soiled/wet. Garment can feel "hot" to wearer
Hard/soft shell combination, in garment. eg SafeHip, Caress	Force shunting and energy absorption effective on non bony subjects. Garment appears to ensure correct positioning of the pads in use.	Very little protection on bony lightweight subjects. Not obvious if shell broken in use, force shunting becomes ineffective. Needs not correct positioning to avoid edge or hard shell shape to lie over the GT. Uncomfortable to lie on during sleeping, and potentially high interface pressures. Garment can be difficult to put on and off, especially for the disabled user. Cosmetically, can appear prominent. Tissue viability problems if garment becomes soiled/wet. Garment can feel "hot" to wearer.
Soft pad. Eg Lyds, HipSaver, KPH	Energy absorption very effective. More self conforming with the subjects skin. More comfortable to lie on. Interface pressures low. Unlikely to break/fracture following a fall.	Unless covered pad material can absorb fluids. Can be bulky over a larger area. Garment/pad more likely to present tissue viability, and incompatible with incontinence aids. Problems of both garment and pad absorb fluids/soiling.
Skin mounted soft pad (In development)	Totally conforming to shape. If shaped and positioned correctly, always covers the GT. Compliance not an issue if nursing staff place as a dressing, 24hrs attachnmet. If protected, can be used in shower/bath. Compatible with incontinence aids.	Needs regular replacement by trained nursing staff (every 14 days?) Correct positioning important. More expensive in pads and nursing time. Detachment may occur in use. Peripheral adhesive strip may ride over GT if incorrectly positioned.

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Fig 1 Examples of pads tested









Effect of shape on force shunting effect. Position of the GT at 0 and 60 degrees hip flexion (4 cm apart)

Fig 4

Pressure over the GT lying on side



Posterior Anterior Left greater trochanter (bare skin, Yellow bar=10cms, 90 Kg male)

Pressure sore over greater trochanter



Fig 3