Hip protectors: recommendations for biomechanical testing—an international consensus statement (part I)

S. N. Robinovitch,

School of Engineering Science and Department of Biomedical Physiology and Kinesiology, Simon Fraser University, Vancouver, BC, Canada

S. L. Evans,

School of Engineering, Cardiff University, Cardiff, UK

J. Minns,

National Health Service, Newcastle, UK

A. C. Laing,

Department of Kinesiology, Faculty of Applied Health Sciences, University of Waterloo, Ontario, Canada

P. Kannus,

Injury and Osteoporosis Research Center, UKK Institute, Tampere, Finland

P. A. Crompton,

Department of Mechanical Engineering, University of British Columbia, Vancouver, Canada

S. Derler,

Laboratory for Protection and Physiology, Swiss Federal Laboratories for Materials Testing and Research (Empa), St. Gallen, Switzerland

S. J. Birge,

Division of Geriatrics and Nutritional Science, Washington University School of Medicine, St. Louis, MO, USA

D. Plant,

Mechanics of Materials Group, Department of Mechanical Engineering, Imperial College, London, UK

Correspondence to: S. N. Robinovitch.

The International Hip Protector Research Group formed in 2007 to address barriers to the clinical effectiveness of hip protectors. This article, the first of a two-part series, represents an evidence-based consensus statement on recommended methods for biomechanical testing of hip protectors. Part II (doi:10.1007/s00198-009-1055-2), which will appear in a future issue of *Osteoporosis International*, focuses on recommended methods for future clinical trials of hip protectors

Conflicts of interest S.N. Robinovitch is a consultant to Tytex A/S, manufacturer of the Safehip line of wearable hip protectors. S.L. Evans was a consultant to the Ascent Group on hip protector design and testing and is currently a consultant to Dow Corning on impact protection materials and testing. A.C. Laing has received funding for conference travel from Tytex A/S. D.P. Kiel has received grants, served on advisory boards, or served on speakers' bureaus for Eli Lilly, Novartis, Merck, Procter and Gamble, Amgen, GSK, Pfizer, Lifeline, and Hologic. P. Kannus has received grant funding, lecturing fees, or consulting fees from Aventis, MSD, Novartis, Pfizer, Respecta, and Roche. S.J. Birge has served on speakers' bureaus for Merck, Novartis, Wyeth and as a consultant to Glaxo-Smith Kline and Pfizer. J.B. Lauritzen was a consultant to Tytex A/S until 2006. R.J. Minns received financial assistance from WinHealth (the European distributors of HipSaver hip protectors) for the construction of the test rig in his laboratory.

I. D. Cameron,

Rehabilitation Studies Unit, Faculty of Medicine, University of Sydney, Sydney, Australia

D. P. Kiel,

Institute for Aging Research, Hebrew SeniorLife-Harvard Medical School, Boston, MA, USA

J. Howland,

Social and Behavioral Sciences Department, Boston University School of Public, Boston, MA, USA, Harvard Injury Control Research Center, Harvard School of Public Health, Boston, MA, USA

K. Khan, and

Centre for Hip Health and Mobility, Faculty of Medicine, University of British Columbia-Vancouver Coastal Health Research Institute, Vancouver, Canada

J. B. Lauritzen

Department of Orthopedics and Internal Medicine, Bispebjerg Hospital, Health Science Faculty, University of Copenhagen, Copenhagen, Denmark

Abstract

Introduction—Hip protectors represent a promising strategy for preventing fall-related hip fractures. However, clinical trials have yielded conflicting results due, in part, to lack of agreement on techniques for measuring and optimizing the biomechanical performance of hip protectors as a prerequisite to clinical trials.

Methods—In November 2007, the International Hip Protector Research Group met in Copenhagen to address barriers to the clinical effectiveness of hip protectors. This paper represents an evidence-based consensus statement from the group on recommended methods for evaluating the biomechanical performance of hip protectors.

Results and conclusions—The primary outcome of testing should be the percent reduction (compared with the unpadded condition) in peak value of the axial compressive force applied to the femoral neck during a simulated fall on the greater trochanter. To provide reasonable results, the test system should accurately simulate the pelvic anatomy, and the impact velocity (3.4 m/s), pelvic stiffness (acceptable range: 39–55 kN/m), and effective mass of the body (acceptable range: 22–33 kg) during impact. Given the current lack of clear evidence regarding the clinical efficacy of specific hip protectors, the primary value of biomechanical testing at present is to compare the protective value of different products, as opposed to rejecting or accepting specific devices for market use.

Keywords

Aged; Biomechanics; Hip Fractures; Materials testing; Prevention; Standards

Introduction

Hip fractures are a major health problem for older adults. Approximately 20% of older adults hospitalized for a hip fracture die within a year and about 50% will suffer a major decline in independence [1, 2]. Fracture risk increases exponentially with age, and given the

aging of the population, the global incidence of hip fracture is projected to increase 4-fold to six million annual cases by 2050 [3].

More than 90% of hip fractures are due to falls, and external “hip protectors” (wearable pads or shields typically embedded in an undergarment) represent an attractive strategy for reducing femoral impact force and preventing hip fractures in high-risk elderly individuals. However, clinical studies have yielded conflicting results on the clinical effectiveness of hip protectors [4–6]. This is thought to be due to several reasons including poor adherence among users in wearing the device (averaging approximately 50%), problems in research design, and lack of accepted techniques to measure the biomechanical performance of hip protectors. Because properly designed clinical trials are very costly, it is important to evaluate hip protectors under laboratory conditions that accurately simulate the clinical setting before embarking on clinical trials.

However, there is a lack of agreed-upon standards for such laboratory tests, and there are conflicting reports on the force attenuation provided by specific devices from researchers using fundamentally different test systems [7–12]. Furthermore, investigators have shown that the force attenuation provided by hip protectors is influenced by features of the test system, such as soft tissue stiffness [13], soft tissue thickness [14], surface geometry [8, 13], and impact velocity [13, 15]. The lack of testing standards has made it difficult for manufacturers to optimize their products and for clinical researchers to select the best available product for use in clinical trials. It has also hindered efforts to educate consumers and introduce market regulation of hip protectors.

The International Hip Protector Research Group (IHPRG) has been working to develop recommendations for (1) standard techniques for measuring the biomechanical performance of hip protectors and (2) the design of future clinical trials of hip protectors. This paper presents our recommendations on biomechanical testing. A companion paper addresses the design of clinical trials.

Methods

The IHPRG was formed in 2007 to address perceived barriers to the clinical value of hip protectors. Funded by the Canadian Institutes for Health Research, the group consists of international experts in biomechanical engineering, epidemiology, orthopedics, and gerontology. We met by regular teleconferences throughout 2007 and 2008, had a face-to-face meeting in Copenhagen in November of 2007, and participated in frequent email discussions.

The current paper is a consensus document from the group concerning recommended characteristics of testing systems for measuring the biomechanical performance of hip protectors. In particular, we focus on recommended techniques for measuring the ability of hip protectors to reduce the peak axial compressive force applied to the femoral neck (which we refer to hereafter as the “peak force” or “peak compressive force”) when worn by a typical older woman who falls from standing height and lands on her hip. We focus on women instead of men because they have a 3-fold greater lifetime risk for hip fracture [16].

We acknowledge that other issues influence the overall value of hip protectors including (but not limited to) their ability to reduce peak force in older men, their ability to reduce peak forces over a range of fall directions, and their ability to reduce the peak magnitude of components of load at the proximal femur other than axial compression (such as bending and torsional moments and shear forces); the durability of the protector to repeated laundering (or repeated impacts); the potential for movement of the protector from its intended location; the effect of variations in temperature and humidity on the provided force reduction; the risk for skin damage related to prolonged use and movement over vulnerable skin; and aesthetic considerations related to device thickness and garment design. However, these issues are not addressed in the current paper.

Below, we provide a brief overview of previously described systems for evaluating the biomechanical performance of hip protectors. We then provide recommendations on the desired characteristics of a “standard” hip protector testing system the elements of which have been incorporated into test systems at three test sites in the UK (the respective laboratories of coauthors Minns, Evans, and Plant). These systems incorporate key design features of other systems [7, 11, 13–15] but are relatively straightforward to construct and duplicate. Several coauthors (Lauritzen, Minns, Evans, Plant, and Robinovitch) have been involved since 2005 in efforts to develop a standard for hip protector testing by the Surgical Dressings Manufacturers Association (SDMA) in the UK, and the SDMA recommendations are similar to those described here.

Results and discussion

Hip protector design philosophy

Hip protectors are designed to reduce peak force at the proximal femur (and fracture risk) by either decreasing the stiffness of the contact site (greater trochanter) or by forming a bridge over the trochanter to shunt the energy of the fall to surrounding regions where it can be absorbed more safely. Hip protectors have traditionally incorporated plastic shells for enhanced energy shunting and force distribution [17, 18]. However, recent attention has shifted to soft shell (foam) protectors which lack a rigid shell and may provide better comfort and adherence [19–21]. In the design of both types of protectors, there is a compromise in selecting a pad thick enough to provide reasonable force attenuation, but not so thick that it negatively affects the wearer’s body image, and is deemed unacceptable to the wearer. The perceived need for a slender profile is the primary constraint to the development of biomechanically effective hip protectors, and several investigators have suggested rapidly deploying “airbag-like” inflatable devices as a future direction for hip protector development [22, 23].

Strength of the proximal femur during a fall

An appropriate measure of the protective value of a hip protector is the amount it reduces the peak compressive force at the proximal femur during a simulated fall below the value that is expected to cause hip fracture in the target population. To determine reasonable estimates for the latter parameter, we reviewed results from 16 studies that reported the “strength” of elderly cadaveric proximal femora tested in a fall loading configuration defined as the

compressive force (measured at either the greater trochanter or acetabulum) that produced fracture [24–39]. These data indicate a profound effect of both age and gender on femoral strength (Table 1). For studies in which male and female data were combined, the median femoral strength averaged across all studies was 3,472 N (range, 2,110 to 4,354 N), and the median standard deviation was 1,534 N (range, 695 to 1,886 N). For studies that reported age-specific values [29], the mean femoral strength was approximately 50% lower for specimens from older than from younger adults (3,770 N for specimens of mean age 74 years (SD=7 years) versus 7,550 N for specimens of mean age 33 years (SD=13 years)). In specimens from older adults (median age=82 years for female and 78 years for male), the median femoral strength was approximately 30% lower for female than male specimens (2,966 versus 4,220 N). Rate of deformation appeared to have a minimum effect on femoral strength with mean values being approximately 10% higher for studies involving loading rates of 100 mm/s or higher when compared with those involving rates of 14 mm/s or less.

Current approaches to hip protector testing

There are various descriptions in the literature of mechanical test systems to evaluate the attenuation in peak force provided by hip protectors during a simulated fall [7–11, 14, 15]. While the approach in designing these systems has generally been to simulate a worse-case fall in a frail older adult, the systems have, in fact, differed substantially in the surface geometry and mechanical properties (mass, stiffness, and damping) of the simulated hip and pelvis, the impact velocity and kinetic energy involved in the test, and corresponding estimates of the force attenuation provided by existing hip protectors. This is due, in part, to the scarcity of biomechanical studies on the dynamics of falls, which represents a crucial research priority. In particular, more information is needed about the fall-induced forces applied to the greater trochanter of the proximal femur at the time of the fall impact. Below, we summarize the best evidence from existing studies in this area.

Effective mass, effective stiffness, impact velocity, and impact energy

The purpose of a fall impact simulator is to provide an accurate estimate of the peak compressive force applied to the proximal femur during a fall and the reduction in force provided by a hip protector. In this section, we discuss how, in order to achieve this, the system must accurately simulate the anatomy of the human pelvis, the impact velocity of the hip just before it impacts the ground, and the effective mass and stiffness of the body during the impact.

We start by considering the simplest possible model capable of describing force generation during impact to the hip. Previous experiments indicate that, during impact to the hip, the body vibrates with a single natural frequency reflecting vertical movement of a single effective mass resting on a parallel spring–damper support [40–43]. In general, the force developed by a spring is proportional to its deflection, while the force developed by a damper is proportional to its velocity or rate of deflection. Evidence also suggests that damping has a relatively modest effect on peak force and may therefore be ignored [44]. Next, consider that, during a fall, the initial potential energy of the body during standing (mgh) is converted first to kinetic energy at impact ($mv^2/2$) and then to elastic strain energy in the body spring ($F^2/(2k)$), where m is the effective mass (in kilograms), h is the fall height

(in meters), v is the impact velocity (in meters per second), F is the peak force (in Newtons), and k is the effective stiffness of the body (in Newtons per meter). Accordingly, the peak compressive force generated during impact in this unpadded case can be estimated as:

$$F_{\text{unpadded}} = \sqrt{2kmgh} = v \sqrt{mk}. \quad (1)$$

Finally, consider that, when an individual wears a hip protector of stiffness k_p (which acts in series with the body spring k), the peak force is:

$$F_{\text{padded}} = v \sqrt{m \left(\frac{kk_p}{k+k_p} \right)}, \quad (2)$$

and the attenuation in peak force provided by the hip protector is:

$$\begin{aligned} \% \text{attenuation} &= 100 * \left(1 - \frac{F_{\text{padded}}}{F_{\text{unpadded}}} \right) \\ &= 100 * \left(1 - \sqrt{\frac{k_p}{k_p+k}} \right). \end{aligned} \quad (3)$$

Equations (1)–(3) clearly show that the attenuation in peak force provided by a hip protector will depend not only on the stiffness of the protector k_p (increasing with decreases in k_p) but also on the stiffness of the body (increasing with increases in k). Furthermore, the baseline peak force will depend on the impact velocity v and effective mass m . Accordingly, in order to provide accurate measures of the protective value of a hip protector, a hip impact simulator must closely match each of these parameters. It is important to note that, while different combinations of effective mass, stiffness, and impact velocity (or drop height) can provide the same baseline force, an overly stiff system will overestimate the reduction in peak force provided by a given hip protector. It will also necessitate the use of too small an effective mass, giving rise to an underestimate of the time to peak force. Conversely, an overly compliant test system will tend to underestimate the reduction in peak force provided by a hip protector.

The question then arises: what are reasonable estimates of effective mass, effective stiffness, and impact energy of the body during a fall on the hip? Experiments involving young adults falling onto gym mats [45, 46] indicate that, when no attempt is made to slow the body's downward velocity during descent (simulating a worse-case fall), the impact velocity of the hip averages 3.01 m/s (SD=0.83 m/s), and the kinetic energy of the entire body at the moment of hip impact averages 307 J (SD=90 J). There is less agreement on the issue of the effective mass and stiffness of the body during impact. We conclude that the anatomic and biomechanical characteristics that determine these values are complex and that more research is required on this topic. To date, the best available estimates are from drop tests (or "pelvis release experiments") which measure the impact response of healthy young adults during low-velocity falls on the hip [41, 42]. These indicate that, in the case of the knee and hand contacting just before the hip, the average effective mass m during impact for young

women is 33 kg (SD=11 kg) or just less than half body mass, and the average effective stiffness k is 39 kN/m (SD=16 kN/m). The effective mass is influenced by all body segments moving with a nonzero vertical velocity at the time of impact to the hip. The effective stiffness is due primarily to three components: (1) the compressive stiffness of the soft tissues overlying the hip region, (2) the compressive stiffness of the pelvic bones themselves, and (3) the stiffness of the articulations between the trunk, pelvis, and lower extremities. The primary limitations of these measurements are that they are derived from young volunteers and that the impact velocity (and thus the peak force and peak deformation) of the hip is small compared with the case of real falls. Clearly, additional research is warranted to measure age-related changes in effective stiffness. However, one can anticipate that slender older adults at greatest risk of hip fracture will have greater effective stiffness resulting from decreased soft tissue over the hip and increased calcification and stiffness of the pelvic articulations, and decreased effective mass. They may have less effective protective responses when landing from a fall (e.g. ability to break the fall with the outstretched hand) and increased velocity at the moment the hip strikes the ground. Accordingly, we suggest that test system utilize an effective falling mass of 28 kg (the (mean + 0.5*SD) measured in young women) with an acceptable range of 22–33 kg), a compressive stiffness for the pelvis of 47 kN/m (the (mean + 0.5*SD) measured in young women) with an acceptable range of 39–55 kN/m), and an impact velocity of 3.4 m/s (the (mean+0.5*SD) measured in young adults). Future research should focus on the development of more advanced test systems, which allow for the adjustment of impact velocity, pelvic stiffness, and effective mass in order to determine how hip protectors perform for individuals of different body types and different fall severities.

Delivering the impact energy: drop tower versus impact pendulum

All test systems use a falling mass to generate impact energy (Fig. 1), which may either fall vertically by a drop tower [7, 9, 14] or in a curved path by a pendulum [11, 15]. Both options are acceptable. However, care is required in the case of a drop tower to avoid binding between the falling mass and the guides during impact, while, in the case of a pendulum, the effective mass and any compliance in the pendulum arm must be factored in when calculating the total effective mass and stiffness, respectively. In both cases, sensors are required to accurately measure the impact velocity of the mass and match this to the desired fall velocity of 3.4 m/s. There are several methods for achieving this, including rotational potentiometers, linear position or velocity transducers, or motion capture systems.

Proximal femur: geometry, mechanical properties, boundary conditions, and orientation

The proximal femur model is clearly a vital component of the test system. A variety of geometries have been used ranging from the composite femur manufactured by Sawbones [11, 14] to a metallic replica of similar geometry [7, 9]. There is a general consensus that the local deformation of the femur is either negligible or can be represented elsewhere as part of an overall system compliance, and so, more durable materials such as steel or aluminum can be used. The boundary conditions on the femur in vivo are complex and not well understood. Previous systems have either supported the femur at a single proximal point [11] or at both distal and proximal locations [7, 9, 14]. Since the point of application of the impact force is close to the femoral neck, the fraction of the peak force that is carried by a distal support is

small, and it seems reasonable to use only a single support, provided the load cell can tolerate some bending moment. In most test systems, the impact force is applied in the plane formed by the axes of the femoral neck and femoral shaft, which corresponds to internal rotation of the femoral neck of about 12° or what Pinilla and colleagues described as a typical body configuration at impact from a sideways fall [37]. The angle of the femoral shaft with respect to the horizontal has been set to either zero (simulating impact to the knee simultaneous with the hip [11]) or approximately 10° [7, 9].

Force measurement and filtering

The primary output from most hip impact simulators is the peak compressive force applied to the proximal femur. Usually this is measured with a single axis load cell located within the femoral neck [11, 15] or acetabulum [14] at a sampling frequency of 1,000 Hz or higher. Alternatives include a triaxial load cell [7] or button load cell at the greater trochanter [9]. Care is required to select a load cell that has a resonant frequency far higher than the characteristic frequencies associated with hip impact, to ensure correct seating and preloading, and to ensure the device is not subjected to excessive off-axis forces.

Low-pass filtering of the force signal is often required to remove higher frequency artifacts superimposed on the main waveform (Fig. 2). However, caution should be exerted in selecting a filter which does not unduly influence the underlying main waveform. Ideally, filtering should be applied in the digital domain, so that the effect of filter parameters can be evaluated. Typically, we find that the energy content of the main waveform is focused at approximately 5 Hz, and that of the secondary (artifact) waveform at approximately 80 Hz. Accordingly, a fourth order, recursive Butterworth filter with a cut-off frequency of 50 Hz effectively attenuates the secondary frequency artifact, while preserving the underlying main waveform. In contrast, a 200 Hz cut-off frequency has little effect in removing the secondary frequency, while a 20 Hz cut-off frequency (not shown in Fig. 2) has too great an effect on the underlying main waveform. In any case, the cut-off frequency must be less than the one-half the sampling frequency to avoid aliasing artifacts.

Surface geometry of the pelvic model and trochanteric soft tissue stiffness

The anatomy and surface geometry of the pelvic model and stiffness of the simulated soft tissues are very important, since these parameters influence the contact area and protrusion of the pad or shield during impact, and the distribution of force to the underlying skeletal structures. More specifically, the manner in which the impact force is ultimately transferred into the bony femur and pelvis is determined by the combination of surface geometry, soft tissue stiffness, and design characteristics of the hip protector. With regard to surface geometry, Minns utilized a CNC-machined form that matched the surface geometry measured on young women having an average body mass index (22.6 kg/m^2) similar to that reported for hip fracture patients [9]. Laing and Robinovitch recently reported 3D coordinates describing the average surface geometry of the hip, buttock, and anterior thigh region of elderly women, which they incorporated into their test system [13]. Derler et al. [7] developed a hip surface geometry based on anthropometric data for a 50th-percentile woman. Most test systems have simulated the compliance of trochanteric soft tissues with foam rubbers or elastomers of varying density [7, 9, 11, 13–15, 47]. However, experimental

data describing the mechanical behavior of the soft tissues around the hip is limited, especially in the frailest elderly who are highest risk for hip fracture. Laing et al. conducted indentation tests to measure the stiffness of trochanteric soft tissue over nine hip regions in elderly women [13]. However, measures were not acquired at high strain rates. Robinovitch et al. conducted impact tests on trochanteric soft tissues harvested from cadavers [48] and provided gross measures of the energy absorption and force attenuation capacity of these tissues and how this varies with tissue thickness. In that study, the thickness of soft tissues at the trochanteric bursa (measured by a needle probe) ranged between 8 and 45 mm, and averaged 24 mm. For a constant impact energy, peak force at the femoral neck decreased with tissue thickness at a rate of 71 N/mm. Three other studies have examined the thickness of soft tissues over the greater trochanter in living older adults. Minns et al. measured this parameter with ultrasound with participants lying on their side and reported an average value of 18 mm in older women who fractured their hips ($n=20$) and 28 mm in an age-matched control group ($n=12$) [47]. Bouxsein et al. [26] determined this parameter from whole-body dual-energy X-ray absorptiometry (DXA) scans acquired with participants lying supine. Average values were 40.4 (SD=16.7 years) for women who suffered hip fracture ($n=21$) and 49.8 (SD=16.8) mm for age-matched controls ($n=42$). Using a similar technique, Nielson et al. [49] reported the trochanteric soft tissue thickness in older men to average 29.1 mm (SD=11.9 mm) for hip fracture patients ($n=70$) and 31.0 (SD=11.5 mm) for controls ($n=222$). Clearly, additional work is required to characterize the regional variation over the hip in geometry and mechanical properties of soft tissues (including compressibility, strain rate dependence, anisotropy, and force-dependant nonlinearities), and to develop surrogate tissues that can accurately simulate this behavior.

Peak force and rise time characteristics

As described previously, the peak force during impact is governed by the impact velocity, the total effective mass, and the total effective stiffness of the body. These same parameters govern the natural frequency of vibration and the time to peak force (or “rise time”). Data from drop tests on volunteers illustrate that, during unpadded impacts, the time to peak force should be around 30 ms and the total impact duration should be around 100 ms [40]. The 30-ms rise time provides an important check of the system “biofidelity” since rigid systems such as that used in EN1621 will provide much shorter rise times [50]. Furthermore, for an impact energy of 250 J, peak force at the femoral neck in the unpadded case should be approximately 4 kN. Together, these characteristics define the overall behavior of the test system. It is important that any proposed system should correctly reproduce these features. As discussed previously (in the section “Strength of the proximal femur during a fall”), a force of 4 kN at the femoral neck is well above the median force required to fracture the proximal femur of older woman, and just below that required to fracture the femur of older men.

Hip protector placement

The position of a hip protector relative to the greater trochanter and femoral diaphysis may strongly influence its capacity to attenuate peak force, and in the case of hard shell designs, the interface pressure between the skin and the protector [47]. Hip protectors may be misplaced from their intended position by shifting of the garment during use, lack of

understanding by the user of the intended position (e.g., greater trochanter versus iliac crest), or shifting of the greater trochanter beneath the skin due to internal/external rotation or flexion/extension of the femur. Accordingly, we recommend that test procedures should incorporate trials where the hip protector is located in several configurations, including (1) positioned according to the manufacturer's instructions, (2) located a specific magnitude and direction away from its intended position (shifted 5 cm in the anterior, posterior, inferior, and superior directions), and (3) positioned in its most likely position during typical use. The latter should be based on measures from at least ten older women (who fit the profile of likely users of hip protectors) while they wear the device. Protectors should be assessed using their recommended garment and method of fixation to the surrogate pelvis.

Testing conditions: temperature, humidity, and prelaundering of hip protectors

Most hip protectors are made wholly or partly from polymeric materials, which may exhibit significant temperature and moisture dependence in mechanical properties (typically decreasing in stiffness with increasing temperature). They should therefore be tested under controlled temperature and humidity. The temperature distribution and humidity around a protector in use will vary with the environmental conditions, the clothing worn over it, and the activities of the user. There may be a pronounced temperature gradient from the inside to the outside, and the humidity may also vary widely. Accordingly, at present, we recommend that protectors should be preconditioned for at least 24 h and tested under standard laboratory conditions for polymer testing of 23°C and 50% relative humidity. However, we also note the need for further research to determine how the capacity of hip protectors to attenuate peak force is affected by pad temperature (skin versus room temperature (32° versus 23°C)) and humidity.

Laundering may also influence the mechanical properties and capacity of hip protectors to attenuate peak force, especially with the high temperature washing and drying that is typical of residential care facilities. Furthermore, many hip protectors are sewn-in and unavoidably washed along with undergarments. We therefore recommend that hip protectors be tested before laundering, and after 50 and 100 wash–dry cycles involving temperatures and detergents typically used in residential care facilities.

Outcome variables and numbers of trials

We recommend that at least five trials be conducted for each test condition (i.e., unpadded and padded) with a time interval of at least 3 min between subsequent trials to allow for rebound from deformation of the hip protector and “soft tissues” of the surrogate pelvis. A record should be made of the peak force and time to peak force from each trial and the mean and standard deviation in these parameters over the repeated trials. These raw data should be reported in any report of hip protector testing along with the calculated percent reduction (or attenuation) in the mean value of peak force between the unpadded the padded conditions.

Maintenance and calibration

Attention should be paid to regular maintenance schedules, calibration tests (including measures of peak force and rise time for various specified test conditions), and inspection and replacement of damaged soft tissue or other components.

Data interpretation and pass/fail criteria

The primary aim of biomechanical testing of hip protectors should be to separate those protectors that are likely to prevent the majority of fractures in the target population from those that are not. Accordingly, hip protectors should be designed so that under typical fall-loading testing conditions, the peak force at the femoral neck is reduced well below the value which typically fractures the proximal femur of older women. This threshold value might be set at the median femoral strength (of 2,966 N, as discussed above), one standard deviation below the median strength ($2,966 - 1,117 = 1,849$ N) or even two standard deviations below the median strength ($2,966 - 2,234 = 732$ N; although this latter criteria may be satisfied only by a rather thick pad or an active inflatable pad). However, before promoting a specific pass-fail criterion for determining the market suitability of hip protectors, clinical studies are required to verify such an approach. Unfortunately, no clinical trials to date have clearly demonstrated that a particular protector is effective to serve as a gold standard for alternative designs. Until such data exist, we suggest that the main value of biomechanical testing is to compare the relative protective value of various devices.

We also recommend that the main outcome variable from testing should be the peak force measured at the femoral neck (or acetabulum or greater trochanter), since there are considerable data on the compressive force that tends to cause failure of the elderly cadaveric femur (as described previously). Alternative outcomes, such as energy absorption in the bone or peak stress (or strain) generated during impact [51], are currently less attractive given our more limited understanding of the energy absorption or state of stress required to cause failure of the proximal femur.

Finally, we again refer the reader to our companion paper, which provides recommendations on the design of clinical trials of hip protectors.

Conclusions

Hip protectors represent a promising method for preventing hip fractures. However, standards are required by both designers and users for test systems to measure the protective value of hip protectors. An appropriate outcome variable from testing is the peak compressive force at the femoral neck and percent reduction in peak force provided by a given hip protector, when compared with unpadded conditions.

To provide reasonable estimates and comparisons of the capacity of hip protectors to attenuate peak force, test systems should accurately simulate the anatomy, effective mass, effective stiffness, and impact velocity of the body during a fall on the hip. Table 2 lists recommended design specifications for test systems based on our review of existing knowledge.

A crucial priority for biomechanics researchers is to conduct experiments to gain an improved understanding of the dynamics of falls and the factors which govern force development. Of specific interest are the mechanical properties and functional anatomy of the soft tissues and bony structures surrounding the hip region, especially in older at-risk populations. Such research will allow for further refinement of hip protector test methods, an

essential step in the evolution of more clinically effective products. Finally, while data are available on the strength of the proximal femur, it is difficult to identify specific pass-fail criteria for hip protectors until clinical trials demonstrate that a particular protector is effective to serve as a gold standard. Until such data exist, the main value of biomechanical testing is to compare the protective value of new and existing hip protectors.

Acknowledgments

This research was supported in part by the Canadian Institutes for Health Research (CIHR) through a Planning/Development Grant from the International Opportunities Program (P. I.: Robinovitch). Drs. Kiel and Birge were supported by a grant from the National Institute on Aging R01 AG18461. Dr. Kannus was supported by Competitive Research Funding of the Pirkanmaa Hospital District, Tampere, Finland.

References

1. Empana JP, Dargent-Molina P, Breart G. Effect of hip fracture on mortality in elderly women: the EPIDOS prospective study. *J Am Geriatr Soc.* 2004; 52:685–690. [PubMed: 15086646]
2. Wolinsky FD, Fitzgerald JF, Stump TE. The effect of hip fracture on mortality, hospitalization, and functional status: a prospective study. *Am J Public Health.* 1997; 87:398–403. [PubMed: 9096540]
3. Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. *Osteoporos Int.* 1997; 7:407–413. [PubMed: 9425497]
4. Parker MJ, Gillespie WJ, Gillespie LD. Effectiveness of hip protectors for preventing hip fractures in elderly people: systematic review. *Bmj.* 2006; 332:571–574. [PubMed: 16513687]
5. Sawka AM, Boulos P, Beattie K, Thabane L, Papaioannou A, Gafni A, Cranney A, Zytaruk N, Hanley DA, Adachi JD. Do hip protectors decrease the risk of hip fracture in institutional and community-dwelling elderly? A systematic review and meta-analysis of randomized controlled trials. *Osteoporos Int.* 2005; 16:1461–1474. [PubMed: 15990949]
6. Kiel DP, Magaziner J, Zimmerman S, Ball L, Barton BA, Brown KM, Stone JP, Dewkett D, Birge SJ. Efficacy of a hip protector to prevent hip fracture in nursing home residents: the HIP PRO randomized controlled trial. *JAMA.* 2007; 298:413–422. [PubMed: 17652295]
7. Derler S, Spierings AB, Schmitt KU. Anatomical hip model for the mechanical testing of hip protectors. *Med Eng Phys.* 2005; 27:475–485. [PubMed: 15990064]
8. Mills NJ. The biomechanics of hip protectors. *Proc Inst Mech Eng [H].* 1996; 210:259–266.
9. Minns J, Dodd C, Gardner R, Bamford J, Nabhani F. Assessing the safety and effectiveness of hip protectors. *Nurs Stand.* 2004; 18:33–38.
10. Parkkari J, Kannus P, Poutala J, Vuori I. Force attenuation properties of various trochanteric padding materials under typical falling conditions of the elderly. *J Bone Miner Res.* 1994; 9:1391–1396. [PubMed: 7817822]
11. Robinovitch SN, Hayes WC, McMahon TA. Energy-shunting hip padding system attenuates femoral impact force in a simulated fall. *J Biomech Eng.* 1995; 117:409–413. [PubMed: 8748522]
12. Lauritzen JB, Askegaard V. Protection against hip fractures by energy absorption. *Dan Med Bull.* 1992; 39:91–93. [PubMed: 1563301]
13. Laing AC, Robinovitch SN. The force attenuation provided by hip protectors depends on impact velocity, pelvic size, and soft tissue stiffness. *ASME Journal of Biomechanical Engineering.* 2008; 130:061005. (9 pages).
14. van Schoor NM, van der Veen AJ, Schaap LA, Smit TH, Lips P. Biomechanical comparison of hard and soft hip protectors, and the influence of soft tissue. *Bone.* 2006; 39:401–407. [PubMed: 16546458]
15. Kannus P, Parkkari J, Poutala J. Comparison of force attenuation properties of four different hip protectors under simulated falling conditions in the elderly: an in vitro biomechanical study. *Bone.* 1999; 25:229–235. [PubMed: 10456390]
16. Cummings SR, Melton LJ. Epidemiology and outcomes of osteoporotic fractures. *Lancet.* 2002; 359:1761–1767. [PubMed: 12049882]

17. Lauritzen JB, Petersen MM, Lund B. Effect of external hip protectors on hip fractures. *Lancet*. 1993; 341:11–13. [PubMed: 8093267]
18. Parkkari J, Kannus P, Heikkilä J, Poutala J, Sievanen H, Vuori I. Energy-shunting external hip protector attenuates the peak femoral impact force below the theoretical fracture threshold: an in vitro biomechanical study under falling conditions of the elderly. *J Bone Miner Res*. 1995; 10:1437–1442. [PubMed: 8686498]
19. O'Halloran PD, Murray LJ, Cran GW, Dunlop L, Kernohan G, Beringer TR. The effect of type of hip protector and resident characteristics on adherence to use of hip protectors in nursing and residential homes—an exploratory study. *Int J Nurs Stud*. 2005; 42:387–397. [PubMed: 15847901]
20. Suzuki T, Yoshida H, Ishizaki T, Yukawa H, Watanabe S, Kumagai S, Shinkai S, Shibata H, Nakamura T, Yasumura S, Haga H. Compliance in use of external protectors for hip fractures among the community elderly in Japan. *Nippon Ronen Igakkai Zasshi*. 1999; 36:40–44. [PubMed: 10332193]
21. Bentzen H, Forsen L, Becker C, Bergland A. Uptake and adherence with soft- and hard-shelled hip protectors in Norwegian nursing homes: a cluster randomised trial. *Osteoporos Int*. 2008; 19:101–111. [PubMed: 17653617]
22. Wu G, Xue S. Portable preimpact fall detector with inertial sensors. *IEEE Trans Neural Syst Rehabil Eng*. 2008; 16:178–183. [PubMed: 18403286]
23. Charpentier PJ. A hip protector based on airbag technology. *Bone*. 1996; 18:S117.
24. Bouxsein ML, Coan BS, Lee SC. Prediction of the strength of the elderly proximal femur by bone mineral density and quantitative ultrasound measurements of the heel and tibia. *Bone*. 1999; 25:49–54. [PubMed: 10423021]
25. Bouxsein ML, Courtney AC, Hayes WC. Ultrasound and densitometry of the calcaneus correlate with the failure loads of cadaveric femurs. *Calcif Tissue Int*. 1995; 56:99–103. [PubMed: 7736330]
26. Bouxsein ML, Szulc P, Munoz F, Thrall E, Sornay-Rendu E, Delmas PD. Contribution of trochanteric soft tissues to fall force estimates, the factor of risk, and prediction of hip fracture risk. *J Bone Miner Res*. 2007; 22:825–831. [PubMed: 17352651]
27. Cheng XG, Lowet G, Boonen S, Nicholson PH, Brys P, Nijs J, Dequeker J. Assessment of the strength of proximal femur in vitro: relationship to femoral bone mineral density and femoral geometry. *Bone*. 1997; 20:213–218. [PubMed: 9071471]
28. Cheng XG, Lowet G, Boonen S, Nicholson PH, Van der Perre G, Dequeker J. Prediction of vertebral and femoral strength in vitro by bone mineral density measured at different skeletal sites. *J Bone Miner Res*. 1998; 13:1439–1443. [PubMed: 9738516]
29. Courtney AC, Wachtel EF, Myers ER, Hayes WC. Effects of loading rate on strength of the proximal femur. *Calcif Tissue Int*. 1994; 55:53–58. [PubMed: 7922790]
30. Courtney AC, Wachtel EF, Myers ER, Hayes WC. Age-related reductions in the strength of the femur tested in a fall-loading configuration. *J Bone Joint Surg Am*. 1995; 77:387–395. [PubMed: 7890787]
31. Eckstein F, Wunderer C, Boehm H, Kuhn V, Priemel M, Link TM, Lochmuller EM. Reproducibility and side differences of mechanical tests for determining the structural strength of the proximal femur. *J Bone Miner Res*. 2004; 19:379–385. [PubMed: 15040825]
32. Heini PF, Franz T, Fankhauser C, Gasser B, Ganz R. Femoroplasty-augmentation of mechanical properties in the osteoporotic proximal femur: a biomechanical investigation of PMMA reinforcement in cadaver bones. *Clin Biomech*. 2004; 19:506–512.
33. Keyak JH. Relationships between femoral fracture loads for two load configurations. *J Biomech*. 2000; 33:499–502. [PubMed: 10768400]
34. Lochmuller EM, Groll O, Kuhn V, Eckstein F. Mechanical strength of the proximal femur as predicted from geometric and densitometric bone properties at the lower limb versus the distal radius. *Bone*. 2002; 30:207–216. [PubMed: 11792587]
35. Lotz JC, Hayes WC. The use of quantitative computed tomography to estimate risk of fracture of the hip from falls. *J Bone Joint Surg Am*. 1990; 72:689–700. [PubMed: 2355030]
36. Manske SL, Liu-Ambrose T, de Bakker PM, Liu D, Kontulainen S, Guy P, Oxland TR, McKay HA. Femoral neck cortical geometry measured with magnetic resonance imaging is associated with proximal femur strength. *Osteoporos Int*. 2006; 17:1539–1545. [PubMed: 16847586]

37. Pinilla TP, Boardman KC, Buxsein ML, Myers ER, Hayes WC. Impact direction from a fall influences the failure load of the proximal femur as much as age-related bone loss. *Calcif Tissue Int.* 1996; 58:231–235. [PubMed: 8661953]
38. Pulkkinen P, Eckstein F, Lochmuller EM, Kuhn V, Jamsa T. Association of geometric factors and failure load level with the distribution of cervical vs. trochanteric hip fractures. *J Bone Miner Res.* 2006; 21:895–901. [PubMed: 16753020]
39. Pulkkinen P, Jamsa T, Lochmuller EM, Kuhn V, Nieminen MT, Eckstein F. Experimental hip fracture load can be predicted from plain radiography by combined analysis of trabecular bone structure and bone geometry. *Osteoporos Int.* 2008; 19:547–558. [PubMed: 17891327]
40. Laing AC, Tootoonchi I, Hulme PA, Robinovitch SN. Effect of compliant flooring on impact force during falls on the hip. *J Orthop Res.* 2006; 24:1405–1411. [PubMed: 16705716]
41. Robinovitch SN, Hayes WC, McMahon TA. Prediction of femoral impact forces in falls on the hip. *J Biomech Eng.* 1991; 113:366–374. [PubMed: 1762432]
42. Robinovitch SN, Hayes WC, McMahon TA. Distribution of contact force during impact to the hip. *Ann Biomed Eng.* 1997; 25:499–508. [PubMed: 9146804]
43. Parkkari J, Kannus P, Heikkilä J, Poutala J, Heinonen A, Sievanen H, Vuori I. Impact experiments of an external hip protector in young volunteers. *Calcif Tissue Int.* 1997; 60:354–357. [PubMed: 9075632]
44. Robinovitch SN, Hayes WC, McMahon TA. Predicting the impact response of a nonlinear single-degree-of-freedom shock-absorbing system from the measured step response. *J Biomech Eng.* 1997; 119:221–227. [PubMed: 9285332]
45. Feldman F, Robinovitch SN. Reducing hip fracture risk during sideways falls: evidence in young adults of the protective effects of impact to the hands and stepping. *J Biomech.* 2007; 40:2612–2618. [PubMed: 17395188]
46. Robinovitch SN, Brumer R, Maurer J. Effect of the “squat protective response” on impact velocity during backward falls. *J Biomech.* 2004; 37:1329–1337. [PubMed: 15275840]
47. Minns RJ, Marsh AM, Chuck A, Todd J. Are hip protectors correctly positioned in use? *Age Ageing.* 2007; 36:140–144. [PubMed: 17272302]
48. Robinovitch SN, McMahon TA, Hayes WC. Force attenuation in trochanteric soft tissues during impact from a fall. *J Orthop Res.* 1995; 13:956–962. [PubMed: 8544034]
49. Nielson CM, Buxsein ML, Freitas SS, Ensrud KE, Orwoll ES. Trochanteric soft tissue thickness and hip fracture in older men. *J Clin Endocrinol Metab.* 2009; 94:491–496. [PubMed: 19017753]
50. European Standard Ref. No. EN 1621-1:1997 E (1997) Motorcyclists’ protective clothing against mechanical impact part 1: requirements and test methods for impact protectors
51. Spierings AB, Derler S. Assessment of hip protectors and corresponding hip fracture risk using stress calculation in the femoral neck. *Med Eng Phys.* 2006; 28:550–559. [PubMed: 16275044]

Fig. 1.
a Drop tower and **b** pendulum-based systems for measuring the capacity of hip protectors to attenuate the peak compressive force applied to the proximal femur during a simulated sideways fall from standing height

Fig. 2.

Effect of filtering on measured impact force. The raw force trace (*solid line*) has a secondary frequency artifact superimposed on the main waveform. A fourth order, low-pass, recursive Butterworth filter with a cut-off frequency of 50 Hz (*dotted line*) removes the secondary frequency arefact, without fundamentally affecting the primary waveform. In contrast, a filter with a 200 Hz cut-off frequency (*dashed line*) has little effect

Results from studies reporting the strength (compressive force required to cause fracture) of the cadaveric proximal femur from older adults in a sideways fall loading configuration

Table 1

Study	Condition	Mean(SD) fracture force (N)			Mean(SD or range) age in years, sample size		
		Women	Men	Mixed	Women	Men	Mixed
Lotz and Hayes, 1990 ^c				2,110(1,060)			69(9); <i>n</i> =24
Courtney et al. 1994 ^c	Deformation rate=100 mm/s			4,100(1,600)			74(7); <i>n</i> =8
	Deformation rate=2 mm/s			3,440(13,30)			74(7); <i>n</i> =8
Bouxsein et al. 1995 ^c				3,680(1,540)			76(59–96) ^b ; <i>n</i> =16
Piñilla et al. 1996 ^c	0° Load angle			4050(900)			79(11); <i>n</i> =11
	15° Load angle			3,820(910)			81(7); <i>n</i> =11
	30° Load angle			3,060(890)			74(11); <i>n</i> =11
Cheng et al. 1997,1998 ^d		3140(1240)	4630(1550)	3,980(1,600)	71(15); <i>n</i> =28	67(15); <i>n</i> =36	69(15); <i>n</i> =64
Bouxsein et al. 1999 ^c		1997(1127)	3593(1614)	2,636(1,534)	82(13); <i>n</i> =16	78(10); <i>n</i> =10	81(12); <i>n</i> =26
Keyak et al. 2000 ^c				2,400 ^a			70(52–92) ^a ; <i>n</i> =17
Lochmuller et al. 2002 ^d		3,070(1060)	4,230(1530)		82(9); <i>n</i> =63	76(11); <i>n</i> =42	
Eckstein et al. 2004 ^d				3,925(1,650)			79(11); <i>n</i> =54
Heini et al. 2004 ^c				2,499(6,95)			76(7); <i>n</i> =20
Manske et al. 2006 ^c				4,354(1,886)			69(16); <i>n</i> =23
Pulkkinen et al. 2006 ^d		2,821 ^a	4,209 ^a	3,472 ^a	82; <i>n</i> =77	79; <i>n</i> =63	81; <i>n</i> =140
Bouxsein et al. 2007 ^c				3,353(1,809)			81(11); <i>n</i> =49
Pulkkinen et al. 2008 ^d	Cervical fx	2,879(1,117)	4,079(1,165)		82(11); <i>n</i> =34	78(11); <i>n</i> =28	
	Trochanteric fx	3,053(976)	5,506(1374)				
Across study average		2,827	4,375	3,392	80	76	76

^a SD not provided

^b Range (not SD) reported

^c Specimens were stored fresh-frozen

^dSpecimens were embalmed in alcohol/formalin

^eSpecimens were stored frozen, but the authors did not specify fresh versus embalmed.

Table 2

Recommended design parameters of biomechanical test systems for measuring the force attenuation provided by hip protectors

PARAMETER	RECOMMENDED VALUE OR TYPE
Basic design	Impact pendulum or drop tower
Effective (drop) mass	28 kg (acceptable range, 22–33 kg)
Effective pelvic stiffness	47 kN/m (acceptable range, 39–55 kN/m)
Soft tissue covering	Polyethelene or polyurethane foam rubber ^a
Minimal thickness of soft tissue covering over the greater trochanter	18 mm
Impact velocity	3.4 m/s ^b
Peak compressive force in unpadded case	3.5–4.5 kN ^c
Time to peak compressive force in unpadded case	30–50 ms
Filtering of force signals	Low pass recursive, cut off frequency=50 Hz

Notes:

^aThe anatomy and surface geometry of the pelvic model should mimic the pelvic anatomy of older adults.

^bImpact velocities of 2 m/s and 4.5 m/s can be used to simulate a soft fall and a more severe fall, respectively. Peak force will scale accordingly.

^cIt is likely that in severe sideways falls of tall individuals, or in falls from considerably greater than standing height (e.g., down stairs), the peak force applied to the proximal femur will exceed 4.5 kN. However, the group's philosophy was to assess the protective value of hip protectors when worn by a typical older woman, falling from standing height.