Efficacy of a Hip Protector to Prevent Hip Fracture in Nursing Home Residents

The HIP PRO Randomized Controlled Trial

Douglas P. Kiel, MD, MPH
Jay Magaziner, PhD
Sheryl Zimmerman, PhD
Linda Ball, PhD
Bruce A. Barton, PhD
Kathleen M. Brown, PhD
Judith P. Stone, MSW
Dawn Dewkett, BS
Stanley J. Birge, MD

Context Past studies of the efficacy of hip protectors to prevent hip fracture in nursing home residents have had conflicting results, possibly due to potential biases from clustered randomization designs and modest adherence to intervention.

Objective To determine whether an energy-absorbing and energy-dispersing hip protector would reduce the risk of hip fracture when worn by nursing home residents.

Design, Setting, and Participants Multicenter, randomized controlled clinical trial in which 37 nursing homes were randomly assigned to having residents wear a 1-sided hip protector on the left or right hip. Participants were 1042 nursing home residents (mean [SD] aged 85 [7] years; 79% women) who consented and adhered to the hip protector use during a 2-week run-in period and were enrolled. Participating facilities were in greater Boston, Massachusetts, St Louis, Missouri, and Baltimore, Maryland from October 2002 to October 2004. Mean duration of participation for nursing home residents was 7.8 months. None were withdrawn because of adverse effects.

Intervention(s) Undergarments with a 1-sided hip protector made of a 0.32-cm outer layer of polyethylene (2.7 kg/m^3) backed by a hard high-density polyethylene shield (0.95 cm) that was backed by 0.9 kg/m^3 of 1.27-kg ethylene vinyl acetate foam. Each facility was visited 3 times per week to assess adherence and provide staff support.

Main Outcome Measure Adjudicated hip fracture occurrences on padded vs unpadded hips.

Results After a 20-month follow-up (676 person-years of observation), the study was terminated due to a lack of efficacy. The incidence rate of hip fracture on protected vs unprotected hips did not differ (3.1%; 95% confidence interval [CI], 1.8%-4.4% vs 2.5%; 95% CI, 1.3%-3.7%; P=.70). For the 334 nursing home residents with greater than 80% adherence to hip protector use, the incidence rate of hip fracture on protected vs unprotected hips did not differ (5.3%; 95% CI, 2.6%-8.8% vs 3.5%; 95% CI, 1.3%-5.7%; P=.42). Overall adherence was 73.8%.

Conclusions In this clinical trial of an energy-absorbing/shunting hip protector conducted in US nursing homes, we were unable to detect a protective effect on the risk of hip fracture, despite good adherence to protocol. These results add to the increasing body of evidence that hip protectors, as currently designed, are not effective for preventing hip fracture among nursing home residents.

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In the United States, nearly 340 000 hip fractures occur per year,[1] more than 90% of which are associated with falls,[2,3] and the number of hip fractures may double or triple by the middle of this century.[4] The highest incidence rates of hip fractures have been reported in nursing home residents[5-7] where 50% of residents fall each year.[8,9]

Factors contributing to hip fracture in the nursing home population differ from those in community-dwelling seniors. After 70 years of age, falls and other indicators of frailty become the dominant determinant of hip fracture.[10] Postural instability may be one of the most important risk factors, based on the finding that falls to the side increase the risk of hip fractures 3- to 5-fold[11,12] due to their impact forces. Reducing the impact of falls onto the hip with the use of hip protectors may be an effective strategy for preventing fractures, particularly in nursing home residents.

For editorial comment see p 454.

Author Affiliations: Institute for Aging Research, Hebrew SeniorLife and Harvard Medical School, Boston, Massachusetts (Dr Kiel and Mss Stone and Dewkett); Division of Gerontology, Department of Epidemiology and Preventive Medicine, University of Maryland, Baltimore (Dr Magaziner); Program on Aging, Disability and Long-Term Care, Cecil G. Sheps Center for Health Services Research and School of Social Work, University of North Carolina at Chapel Hill (Dr Zimmerman); Division of Geriatrics and Gerontology, Washington University School of Medicine, St Louis, Missouri (Drs Ball and Birge); Maryland Medical Research Institute, Baltimore (Drs Barton and Brown).
Corresponding Author: Douglas P. Kiel, MD, MPH, Director Medical Research, Institute for Aging Research, Hebrew SeniorLife, 1200 Centre St, Boston, MA 02131 (kiel@hrca.harvard.edu).

Hip protectors have been designed to either divert the energy of a fall (hard-shell type) or to absorb the energy of a fall (foam type). If effective, the use of hip protectors would have immediate effects on fracture rates, in contrast to osteoporosis medications, which rely on a gradual increase in bone mineral density and a change in the rate of bone turnover. In addition, the efficacy, expense, and adverse effects of these medications have not been examined in nursing homes.

Results from efficacy trials of external hip protectors conducted outside the United States have been conflicting. Recent meta-analyses concluded that the effectiveness of hip protectors in an institutional setting was uncertain.[13,14] The pooled data from cluster randomized trials in which nursing home units were randomized to use hip protectors or not, showed evidence of a statistically significant reduction in incidence of hip fractures in the groups allocated to hip protectors (relative risk, 0.77; 95% confidence interval [CI], 0.62-0.97), whereas the significant reduction in hip fracture was not apparent on pooling only the studies in which individuals were randomized (relative risk, 0.86; 95% CI, 0.54-1.34).[14] Cluster randomization may introduce methodological bias. The nursing home or unit designated for intervention may differ from the control facility or unit with respect to hip fracture rates, awareness of falls, and aggressiveness of fall-prevention programs.[15]

In addition to differences in efficacy trial study design, the mechanical characteristics of hip protectors used in previous trials may have contributed to conflicting results. In many nursing home residents, the greater trochanteric prominence projects above the plane of the hip as a result of muscle atrophy. The use of a hard-shell energy-shunting type of hip protector without sufficient convexity may result in the protector coming in contact with the trochanteric prominence because of a lack of a surrounding soft-tissue base. As a result, the impact force of a fall would be transmitted directly to the proximal femur instead of being shunted to the surrounding soft tissue. It is not clear that biomechanical testing of hard-shell hip protectors has adequately accounted for the role of the soft tissue surrounding the hip.[16-18] Finally, adherence with required hip protector use was not well monitored and was relatively low in most previously reported trials.[19,20]

Because of the continued controversy surrounding randomization approaches and the efficacy of hard-shell external hip protectors, we performed a randomized controlled clinical trial of an energy-absorbing/shunting hip protector using a unique study design. The Hip Impact Protection PROject (HIP PRO) was designed to test the efficacy of a biomechanically tested energy-absorbing/shunting hip protector[21] in reducing hip fracture incidence among nursing home residents. The hip protector was selected based on its performance in a pilot study and biomechanical testing that demonstrated superior capacity to reduce peak impact force in simulated drop-weight experiments.[21] Nursing home residents wore a hip protector on 1 hip only so that each participant served as his or her own control. This design was based on data showing that right and left hip fractures occur with equal frequency[22] and it eliminated the biases inherent in cluster randomization and in nonuse of blinding of treatment between individual participants. This study also was designed to better ascertain adherence with hip protector use by incorporating 3 weekly unannounced visits to all participants.

METHODS

Nursing Home Recruitment, Randomization, and Staff Training

HIP PRO was conducted at 3 clinical centers and a data coordinating center (Hebrew Rehabilitation Center, Boston, Massachusetts, University of Maryland, Baltimore, and Washington University, St Louis, Missouri; and Maryland Medical Research Institute, Baltimore). It was approved by the institutional review boards at the participating sites and data collection and resident safety were monitored at 6-month intervals by an independent data and safety monitoring board. There were no prespecified formal guidelines for recommending modification or termination of the trial.

Research staff at each clinical center recruited nursing homes giving consideration to the following criteria: (1) geographic proximity to the clinical center; (2) number of licensed beds (ie, 100 or greater); (3) evidence from discussions with nursing home administration and staff that they would support and adhere to the HIP PRO research protocol; (4) past research participation; (5) low usage rate of agency temporary personnel; (6) established reputation in the community; and (7) a review of quality indicators available at http://www.medicare.gov/nhcompare. Beginning in October 2002, the clinical center teams began enrolling nursing homes into the study and obtaining Federalwide Assurance (Office for Human Research Protections, US Department of Health and Human Services) for each facility. A total of 37 nursing homes were recruited and each was randomly assigned as a left- or right-padded facility. Given the flow of garments through facilities, left or right assignment helped staff accurately track and support resident adherence without also having to recall the side to be protected. When a facility was ready to be randomized, a call to the coordinating center was made. Designation for newly enrolled facilities as left- or right-padded was based on the number of licensed beds in the nursing home and the number of previously enrolled facilities that were left- vs right-sided. In each participating nursing home, all residents wore the external hip protector on the same side. To keep the number of residents balanced between right and left hip protection across all nursing homes, a dynamic allocation procedure was adopted. This method enabled the sequential recruitment of nursing homes. Using Monte Carlo simulations, we determined that the

randomization procedure would achieve a balance within 5% of a 50-50 split more than 70% of the time.[23]

Before enrolling residents, the clinical centers delivered in-service training sessions to nursing home staff across all 3 shifts. During these sessions, nursing home staff was instructed as to how the hip pads should be worn and how the pads and garments should be laundered. A strong emphasis was placed on the importance of proper hip pad use 24 hours per day. Staff was told that our research team would visit residents 3 times each week to help with any problems that arose during the study.

Recruitment of Residents

Sample size calculations indicated that if the rate of hip fracture in protected hips was 50% lower than the expected rate of fracture in unprotected hips (2.3 hip fractures/100 hip-years of follow-up,[7]) and if resident adherence was only 50%, 546 individuals would be needed to generate 1632 hip-years of observation over the 3-year follow-up period. This sample size would provide 90% power to detect a 50% reduction in fracture rates in the protected hip.

Due to the expected high rate of resident withdrawal from the study (ie, from death, transfer, loss of mobility), residents who withdrew were replaced to maintain a reasonably constant census of active residents. Residents who became ineligible during participation (eg, became totally bed bound) were also withdrawn from the study. Thus, within a participating nursing home, resident enrollment was a 2-stage process. Beginning in October 2002, when the first nursing home was enrolled, screening of all facility residents was followed by enrollment of eligible consenting residents. After this initial facility-wide screening, periodic screening of all newly admitted residents was carried out through the end of the study in October 2004.

Screening to determine resident eligibility was a 3-tiered process conducted by trained research assistants, and involved chart review, nursing home staff interviews, and a brief physical examination. The physical examination was not conducted until informed consent was obtained. In each enrolled nursing home, research staff initially identified all residents who met the following inclusion criteria: (1) long-stay resident (not in Medicare-type rehabilitation); (2) evidence of an attempt to get out of their chair or bed or to walk without human assistance in the past 4 weeks; (3) older than 65 years of age; (4) absence of a terminal illness expected to result in death in less than 6 months or a severe illness resulting in the resident being bed bound; (5) absence of a history of bilateral hip fractures or hip replacement surgery; (6) absence of a contagious disease necessitating isolation procedures; (7) absence of pressure ulcers, blisters, or skin tears over bony prominences that would be covered by the hip protector garment; (8) hip circumference of 122 cm or less; (9) absence of a nursing home staff recommendation not to enroll a resident because of behavior pertaining to adherence to the protocol (eg, not willing to wear undergarments).

Competency of eligible residents to provide informed consent was ascertained from nursing home staff. Written consent was obtained directly from residents who were considered competent. For residents considered to be incompetent, the designated responsible party was contacted by letter, telephone, and/or in person to obtain consent. All consenting residents who were capable of responding were administered a global measure of cognitive function (the Short Blessed Test [SBT][24]). For those residents considered competent by the nursing home staff who scored 12 or greater on the SBT, informed consent was also obtained from the designated responsible party (a score greater than 12 corresponds with a Mini Mental Status Examination[25] score of 19, a level of cognitive impairment that most would agree would suggest the need for consent from a responsible party). For those residents considered incompetent by the nursing home staff, but who scored less than 12 on the SBT, informed consent was obtained from the resident as well. After consent was obtained, residents' hips were measured and examined for signs or symptoms of past or present hip fracture/replacement. A brief skin examination was also done to look for skin breakdown in the area covered by the hip pad garment.

All consenting residents participated in a 2-week run-in trial to exclude individuals with poor adherence. During this run-in period, research staff made 6 or more unannounced visits to check for adherence. If a resident was found not wearing the hip protector correctly at more than a third of the random visits by the research staff during the run-in period, the resident was withdrawn from the study. However, if the reason for nonadherence was because of nursing home staff actions or garment/hip protector problems, an additional 2-week adherence run-in period was permitted after this problem was corrected. The trial adherence period also provided a means of evaluating cognitively impaired residents' willingness to wear the pads and garments ("assent").

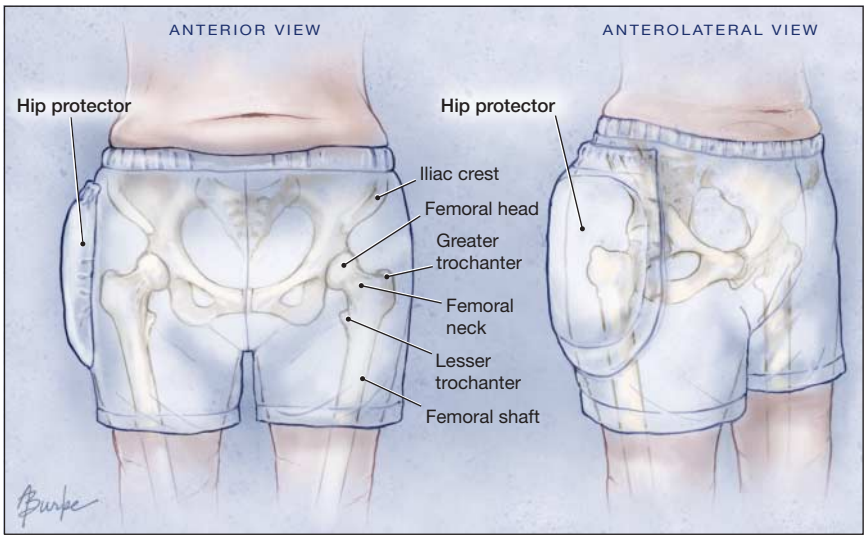
Baseline Assessment

The baseline assessment for all residents consisted of the administration of the SBT and a review of select Minimum Data Set items. Race/ethnicity was recorded from the nursing home record. Cognitively intact residents completed a brief interview about attitudes related to falling, body image, and the use of hip protectors. We were particularly interested in whether wearing hip protectors might reduce the fear of falling. Residents were asked about their fear of falling at baseline using a brief, validated, 8-item self-report measure[26] that generated an overall score ranging from 1 (least fear) to 5. The assessment was repeated every 6 months. The SBT was not readministered for residents who scored 17 or more at baseline.

Hip Protector and Garment

The hip protector was made of a 0.32-cm outer layer of 2.7-kg/m^3 poly-

Figure 1. Right-sided Hip Protector in Standard Pull-up Underwear



ethylene vinyl acetate foam, backed by a hard high-density polyethylene shield, which in turn was backed by a 0.95-cm layer of 0.9-kg/m^3 polyethylene vinyl acetate foam. The pad dimensions were 11.43 cm × 16.51 cm × 1.91 cm. Garments with pad pockets on 1 side were available in sizes ranging from small to triple-extra large. Garments were made of a lycra/cotton blend that was durable in multiple commercial laundry washings. Several garment types were available including a standard pull-up underwear (FIGURE 1), a garment with a baffled pocket inside for cognitively impaired residents who might attempt to remove the pad, a style with snaps to afford easy access to changing of incontinence products, a fly front, and an open-crotch design for use in facilities where nighttime dressing practices required airing of the perineal area. Each resident was provided as many garments as needed for use around-the-clock, allowing for soilage, laundry turnaround time, losses, and deterioration over time.

Assessment of Adherence and Adverse Events

During the trial (including the 2-week run-in period), participating residents were visited 3 times per week by clinical center research staff to assess adherence. These visits were unannounced and conducted at times across all nursing shifts and days of the week. At each visit, research staff checked to determine if the resident was wearing the pad correctly, whether there were sufficient supplies of garments and pads, and whether there were any falls or adverse events related to the hip protector. If the resident was not wearing the hip protector for any reason, the resident was considered nonadherent. Percent of visits adherent was calculated as the number of visits during which a participating nursing home resident was found to be correctly wearing the garment and pad, divided by the number of research staff visits to the resident. Percent adherence provided a measure of exposure to hip protection against fracture and included nursing homes in which policy required no nighttime garment use (6 of the 37 nursing homes). Research staff was trained to identify and address situations resulting in poor adherence. Multiple strategies were used to motivate the nursing home staff and to engage their support in helping residents comply with wearing the hip protectors. Adverse events monitored were skin lesions overlying bony prominences in areas covered by the hip protector garments and development of immobility for which no physical cause could be ascertained.

Primary Outcome Variable

The primary outcome was hip fracture defined as a fracture of the femoral head, neck, or intertrochanteric region extending as far as the level of the lesser trochanter regardless of the presence of a fall. Fractures in regions below the lesser trochanter, around a prosthetic hip device, and chip fractures were not included. Fractures occurring around an internal hip fixation device were included. Each suspected fracture was reviewed by a geriatrician and orthopedic surgeon who were blinded to the side that was padded. All reviewers were members of a clinical end points committee, which consisted of 2 geriatricians, 2 orthopedic surgeons, and 1 musculoskeletal radiologist. The reviewers decided that (1) a fracture consistent with the study criteria had taken place; (2) no such fracture had taken place; or (3) there was insufficient information to make a decision. If the first 2 reviewers did not agree, a third reviewer evaluated the case. If 2 of 3 reviewers could not agree, the full clinical end points committee adjudicated the case.

To ensure complete ascertainment, a hip fracture hotline telephone number was made available and communicated to all nursing staff in all participating nursing homes. Also, research staff regularly reviewed charts for suspected fracture, especially if a resident's behavior suggested a new occurrence of pain or immobility. For each suspected hip fracture report, research staff spoke to nursing home staff to determine hip protector adherence at the time of the event. In practice, many of the hip fractures were discovered by research staff during their routine weekly visits because nursing home staff failed to notify our research team. In 2 instances, our research staff identified residents with hip fractures not known to nursing home staff. Whenever a hip fracture was suspected, research staff completed a hip fracture case report form, and obtained all medical records from the nursing home and hospital, including nurses notes, radiology reports, operative reports, and discharge summaries. These were deidentified and then sent for ad-

judication to the clinical end points committee. In addition to hip fractures, all falls were ascertained from each facility's fall-reporting system and personal interviews of residents and staff.

Statistical Procedures

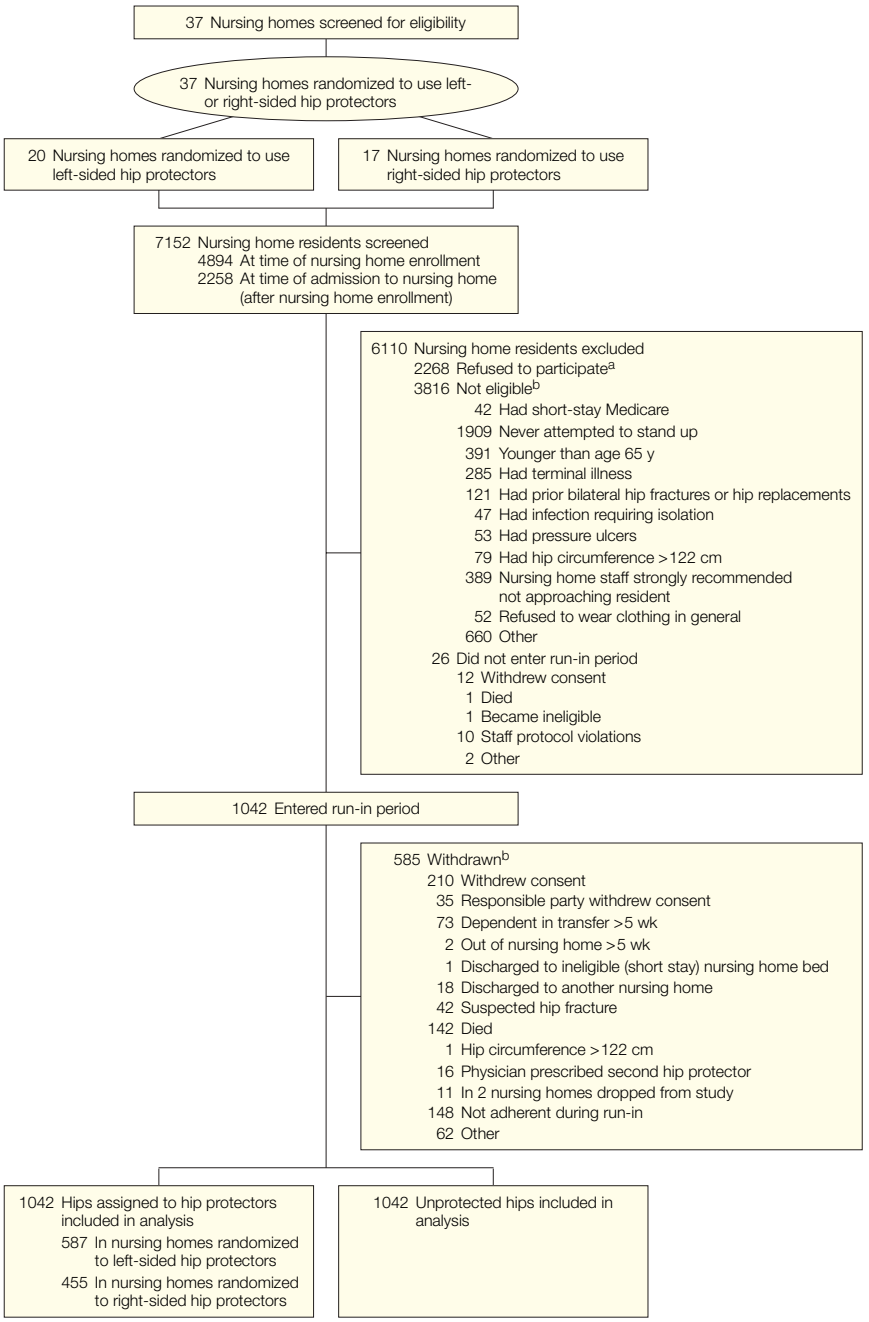
Each suspected fracture was classified as being in the protected hip, unprotected hip, neither (ie, no fracture), or both hips. Because a resident's 2 hips are not independent, and thus violate the independence requirement of the standard χ^2 test, the main analysis of the primary outcome used the Durkalski-adjusted McNemar test to assess the difference in the proportion of fractures in unprotected and protected hips. The McNemar test takes into account the lack of independence between the 2 hips and provides an unbiased test statistic.[27] Incidence rate of hip fracture was calculated by dividing the number of fractures on protected and unprotected hips by the hip-years of observation. The hip-years of observation for each resident was calculated as the number of years from the time a resident entered the 2-week trial period until either unsuccessful completion of the run-in trial period (censored at end of failed run-in period), death, withdrawal, hip fracture or date of the end of the study. We calculated CIs for the hip fracture incidence rate by obtaining the CI for the expected number of events based on a Poisson distribution and then dividing each confidence limit by the number of hip-years of observation.[28] Interim monitoring bounds were calculated for the McNemar test of hip fractures based on an α-spending function[29] and using O'Brien-Fleming-style[30] monitoring bounds.

RESULTS

As shown in FIGURE 2, during the initial screening across all 37 participating nursing homes, 4894 long-stay nursing home residents were identified. An additional 2258 were screened on later admission to the nursing homes. Of the total 7152 screened, 2268 refused participation, leaving 4884 who were screened for eligibility according to the inclusion criteria (previously described).

Of these residents, 3816 were ineligible, leaving 1068 eligible for whom informed consent was obtained. An additional 26 residents failed to enter the

Figure 2. Progress of Participants Through the Trial



[a] Refusals are indicated first because screening for eligibility was a multistage process in which participants could refuse while being screened for eligibility. Reasons for nonparticipation were as follows: unable to make contact with responsible party 26.7%; no interest 21.6%; too burdensome emotionally 13.5%; too burdensome physically 38.2%.
[b] Multiple reasons for ineligibility and for withdrawal could be given.

Table 1. Baseline Characteristics of Enrolled Residents

Characteristic	Consenting Participants (N = 1042)[a]
Women	821 (78.8)
Race/Ethnicity	1040
White	894 (86.0)
Black	142 (13.7)
Asian	1 (0.1)
American Indian	2 (0.2)
Other	2 (0.2)
Hispanic	8 (0.8)
Age, mean (SD), y	85.3 (7.4)
Body mass index, mean (SD)[b]	24.4 (4.5)
Short Blessed Test score, mean (SD)	21.5 (9.0)
Physical functioning	
Transfer	
Independent	415 (40.2)
Supervision	121 (11.7)
Limited assistance	262 (25.4)
Extensive assistance	177 (17.2)
Total dependence	56 (5.4)
Activity did not occur	0
Walk in room	
Independent	395 (38.3)
Supervision	171 (16.6)
Limited assistance	190 (18.4)
Extensive assistance	95 (9.20)
Total dependence	11 (1.10)
Activity did not occur	169 (16.4)
Walk in corridor	
Independent	322 (31.2)
Supervision	214 (20.8)
Limited assistance	185 (17.9)
Extensive assistance	88 (8.5)
Total dependence	12 (1.2)
Activity did not occur	210 (20.4)
Locomotion on unit	
Independent	374 (36.3)
Supervision	235 (22.8)
Limited assistance	194 (18.8)
Extensive assistance	109 (10.6)
Total dependence	111 (10.8)
Activity did not occur	8 (0.8)
Walk off unit	
Independent	217 (21.0)
Supervision	208 (20.2)
Limited assistance	176 (17.1)
Extensive assistance	102 (9.9)
Total dependence	270 (26.2)
Activity did not occur	58 (5.6)
Mobility No. (% with ability)	
Uses cane/walker/crutch	458 (44.5)
Resident wheels self	314 (30.5)
Other person wheels resident	400 (38.8)
Wheelchair primary mode of transportation	370 (35.9)
None of the above	293 (28.4)

(continued)

run-in period. Of the residents who did enter the run-in period, 587 (56.3%) were from nursing homes that had been assigned to be left-padded and 455 (43.7%) were from nursing homes that had been assigned to be right-padded.

Residents who participated were older than residents who did not participate (aged 84.8 years vs 83.2 years; *P* value $<.001$), sex did not differ between the 2 groups (79.4% women vs 78.2% women; *P* value=.47), and history of hip fractures did not differ between groups (16.7% vs 15.4%; *P* value=.36). However, the need for consent by a responsible party was more common in eligible residents agreeing to participate than in residents who declined participation (88.0% vs 74.6%; *P* value $<.001$).

After the initial screening for eligibility within a nursing home, periodic screening of newly admitted residents was carried out throughout the remainder of the study. Thus, 267 additional nursing home residents were recruited into the study during these later screenings.

Mean resident age was 85 years. Nearly 80% of the sample were women, and 86% were white (TABLE 1). The mean SBT score was 21.5, indicating that on average residents had significant cognitive impairment. Less than half of the study residents were able to independently transfer or walk in their room, the corridor, nursing unit, or off the nursing unit. Bladder continence most or all of the time was present in only 41.5% of residents and bowel continence, in only 57%. Hip replacements (6.6%) and hip fracture histories (15.7%) were relatively uncommon despite falls in the last 30 days in approximately 29% of residents. The use of osteoporosis medications such as bisphosphonates was uncommon (6%).

At the time of the first planned interim analysis (20 months of follow-up), the data and safety monitoring board recommended termination of the study due to lack of efficacy and the low probability of being able to demonstrate efficacy in the remaining years of the study. Three approaches were taken to assess the "futility" of continuing the

study. First, we observed that the CIs for the incidence rates of hip fracture on padded and unpadded sides substantially overlapped. Second, we estimated the power to detect the originally proposed effect size if the study were continued, and found that to achieve this effect size, we needed to observe 29 fractures in the unpadded hips and 1 fracture in the padded hips in the remaining 945 person-years of study. Finally, we used EAST 2000 version 4 (Cytel Software, Inc, Cambridge, Massachusetts) to determine the probability of crossing the boundary of futility with the β-spending function proposed by Pampallona, Tsiatis, and Kim.[31] With approximately 33% of data accumulated, the probability of nonfutility was 0.21. At the current rate of β spending, the next look at the data (when approximately 67% of the data are accumulated) would produce a significant futility, allowing us to reject the alternative hypothesis.

At the time the study was terminated in October 2004, 1042 nursing home residents had contributed a total of 676 person-years of observation. The mean participation time was 7.8 months. The overall adherence was 73.8%, and 32.2% of residents had adherence exceeding 80%. As shown in FIGURE 3, adherence was initially about 60%, but by the sixth month of the study adherence rose to 80% and then slowly decreased to less than 70% by the end of the study. Excluding assessments at night in facilities where policy did not permit nighttime use, the adherence was 78.4%, and 40.9% of residents had adherence exceeding 80%.

In the intent-to-treat analysis (N=1042), the incidence rate of hip fracture on protected hips (3.1%) did not differ from the incidence rate on unprotected hips (2.5%; $P=.70$ using the Durkalski-adjusted McNemar test for clustered matched-pair data; TABLE 2; FIGURE 4). Similarly in the per protocol analysis for the 334 residents with greater than 80% adherence, the incidence of hip fracture on protected hips (15 hip fractures/284 hip-years of observation; 5.3%) did not differ from that on unprotected hips (10 hip fractures/284 hip-years of observation; 3.5%; $P=.42$; Table 2). Finally, when we looked at only those residents who were reported by staff to have been wearing the hip protectors at the time of the hip fracture, there were 13 hip fractures on protected hips and 7 hip fractures on unprotected hips. Nursing home staff reported that 6 of the hip fractures occurred on protected hips when residents were not wearing the pad and 7 occurred on unprotected hips when residents were not wearing the pad. For the remaining 5 hip fractures, information on whether a resident was wearing the hip protector was either missing or unknown. We also performed an analysis stratified by mobility level at baseline and observed no difference (all P values $>.30$) between the treatment effect of the pads within each mobility group (ie, independent mobility or mobility with limited assistance compared with wheelchair-bound or mobility with substantial assistance). The differences in the incidence rates between padded and unpadded hips were in the same direction in both mobility groups and the absolute differences were similar (3.8% in padded hips and 2.9% in unpadded hips in the independent mobility group and 2.4% and 2.1%, respectively, in the mobility-dependent group).

There were 2470 reported falls during the 20-month study period. Residents sustained a mean of 3.9 falls per year and 566 of 1042 residents (54.3%) fell at least once. In 184 participants (17.7%) who were cognitively able to answer questions regarding fear of falling at baseline, the mean fear of falling score was 2.6 (SD=0.9) on the 5-point scale. Of these, 73 residents had a fear-of-falling score at follow-up (mean=2.4, SD=0.80) and 67 residents had a score at both time points. The mean change in the fear-of-falling score from baseline to follow-up in residents who scored at both time points was 0.22 (SD=0.67) and was nonsignificant ($P=.78$).

Sixteen skin-related adverse events were reported. None were judged to

Table 1. Baseline Characteristics of Enrolled Residents (cont)

Characteristic	Consenting Participants (N = 1042)[a]
Incontinence	
Bladder	
Continent	305 (29.60)
Usually continent	123 (11.9)
Occasionally incontinent	123 (11.9)
Frequently incontinent	196 (19.0)
Incontinent	284 (27.6)
Bowel	
Continent	498 (48.3)
Usually continent	90 (8.7)
Occasionally incontinent	91 (8.8)
Frequently incontinent	112 (10.9)
Incontinent	240 (23.30)
History of hip replacement	69 (6.6)
History of hip fracture	163 (15.7)
Taking osteoporosis medications	
Bisphosphonates	62 (6.0)
Estrogen	15 (1.5)
Calcitonin	39 (3.8)
Selective estrogen-receptor modulators	10 (1.0)
Prescription vitamin D	95 (9.2)
History of fall in last 30 days	301 (29.2)
Fear-of-falling score, mean (SD)	2.6 (0.9)

[a] Represents No. (%) unless otherwise noted.
[b] Body mass index calculated as weight in kilograms divided by the square of height in meters.

be "possibly related" to the use of the hip protector garment and pad. No adverse changes in mobility occurred due to the wearing of the garment and pad.

COMMENT

In this first clinical trial (to our knowledge) of an energy-absorbing/shunting hip protector conducted in US nursing homes, we were unable to detect a protective effect on the risk of hip fracture, despite successful recruitment, retention, and adherence to the protocol. To determine if this was related to adherence, we also performed a per-protocol analysis in participating nursing home residents who were at least 80% adherent, which confirmed the lack of a protective effect. No study participants were adversely affected in terms of skin problems or mobility, by wearing the garment and pad.

Several unique aspects of this trial distinguish it from previous studies. First, the study design, which used 1-sided hip protectors in all participants, allowed each participant to serve as his or her own control. In this way we avoided biases that have been present in previous trials that have either randomized residents within a facility or units within a facility.[15] In such designs, staff may have differentially cared for the treated nursing home residents compared with the control residents. A second major strength of this study was the use of a run-in period. In clinical practice, health care providers typically follow this approach of prescribing a treatment on a trial basis, and if it is successfully implemented without adverse effects or without objection by residents who have dementia, the treatment can be continued. Third, to our knowledge this study had the most comprehensive and precise way of monitoring and measuring adherence ever reported. Our research staff made 3 random visits per week to each resident during the course of the study throughout all nursing home shifts.

Our results confirm the conclusions of a recent Cochrane systematic review that found no evidence of hip protector efficacy.[14] To date, results of 13 randomized controlled trials have been published, of which 8 studies (including our own) did not demonstrate a statistically significant reduction in hip fracture incidence.[32-39] In the Cochrane review,[13] the authors concluded that hip protectors were not effacacious in studies randomized by individual patient within an institution,

Figure 3. Nursing Home Resident Adherence to Required Use of the Hip Pad, October 2002-October 2004

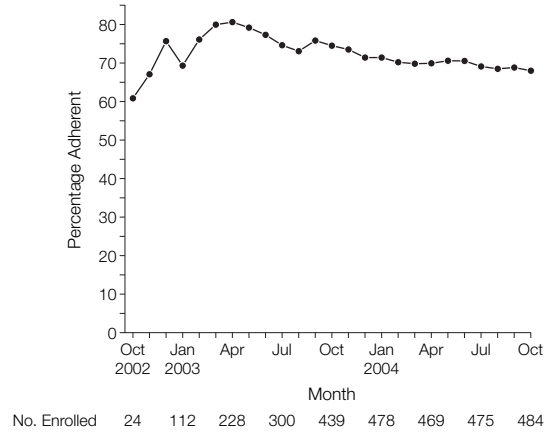
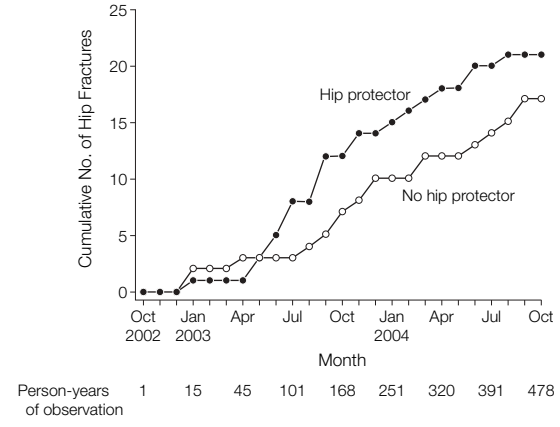


Table 2. Hip Fractures on Protected vs Unprotected Sides

	Intent-to-Treat Analysis (N = 1042)		Per-Protocol Analysis (n = 334)[a]	
	Protected	Unprotected	Protected	Unprotected
No. of hips fractured	21	17	15	10
Hip-years of observation	676		284	
Incidence rate (95% confidence interval)	3.1 (1.8-4.4)	2.5 (1.3-3.7)	5.3 (2.6-8.0)	3.5 (1.3-5.7)
P value	.70		.42	

[a] Included only residents with mean adherence of 80% or greater.

Figure 4. Number of Hip Fractures on Hips Assigned to Padded Side and on Hips Assigned to Have No Pad.



or living independently. In contrast, data from cluster randomized studies indicated that for residents in institutional care, where hip fracture rates are high, hip protectors appeared to reduce the incidence of hip fractures.

The different conclusions drawn from clustered and nonclustered randomized trials of hip protectors underscore the methodologic biases in the design and execution of cluster randomized trials.[15] While our study used clustering to assign the side that was protected, the design differed significantly from the 5 studies that found significant reductions in hip-fracture risk from the use of 2-sided hip protectors.[40-44] It is possible that our results differed from these positive studies because each resident served as his or her own control, thereby eliminating the inherent potential for bias that was present in these previous trials. Likely sources of bias include differences between matched facilities at baseline and differences in nursing home resident comorbidities that influence fall risk. More importantly, in all previous hip-protector trials, the nursing staff in nursing home facilities were not blinded to treatment group. This may have led to differential co-interventions or other practices that could have biased the results in favor of the active treatment. The importance of these biases is underscored by the observation that the same hip protector, Safehip, reduced hip fractures in 2 cluster randomized trials[43,44] but did not reduce hip fractures in a large trial that randomized individuals.[38]

Further differences between HIP PRO and previous studies may have resulted from the type of hip protector used. Most previous studies used the hard-shield hip protector such as Safehip, which because of its rigid structure is not likely to be worn at night when 35% of hip fractures occur.[6] HIP PRO used a more comfortable energy-absorbing/shunting hip protector with which generally higher adherence and nighttime use was possible. At the time the trials began, this hip protector, which is currently not commercially available, had been demonstrated to reduce peak impact forces to below the fracture threshold of the hip of an elderly individual.[21] Although other pads have tested favorably in simulated fall conditions in laboratory settings,[17,18,21,45-47] differences in testing conditions and types of testing configurations have made it difficult to determine the optimal pad design for use in clinical trials. These observations raise concerns about the efficacy of the other commercially available force-absorbing pads that performed less well under the same test conditions.

Our study had several potential limitations. First, the pad we chose, while believed to be the best available at the time of the study based on biomechanical testing, may not have been good enough to prevent hip fractures. Since the time our trial began, other pads have become available and are being tested. Second, the nursing homes participating in our study are not necessarily representative of all US nursing homes. We selected larger-sized facilities in which our study was likely to succeed (nursing homes with previous research experience, higher quality indicators, and proximity to large academic centers). However, our study was intended to be an "efficacy" study and not an "effectiveness" study. This is especially so because of the use of 1-sided hip protectors. Our study design, while overcoming potential biases of cluster randomization and individual randomization, does not completely generalize to the clinical setting where 2-sided hip protectors are used. Even adherence data for 1-sided hip protector use may not be generalizable to the setting of 2-sided hip protector use. Nevertheless, there is no reason to believe that the biomechanical properties of a pad used only on 1 side would be affected by lack of a pad on the opposite hip. However, we cannot exclude the possibility that having only 1 hip protected could have modified the propensity to fall to the protected side either because of the mechanical positioning of the pad or because of sensory cues from the pad that altered gait. Also, we cannot exclude the possibility that residents purposely modified their gait to avoid falls or, in the midst of a fall, tried to fall on the side of the pad. Given the high prevalence of cognitive impairment in the sample, it is difficult to conceive that this could have occurred.

Last, we used a team of research assistants who visited each resident 3 times a week to troubleshoot and support nursing home staff attending to residents participating in the trial. This took considerable time, energy, and patience that may have led to the excellent adherence observed in the study, which may not be as high in the real-world setting. This study evaluated factors related to adherence, which will be informative regardless of the number and type of pads used.

In summary, this large multicenter clinical trial failed to demonstrate a protective effect of a hip protector on hip fracture incidence in nursing home residents despite high adherence, confirming the growing body of evidence that hip protectors are not effective in nursing home populations. With the development of better pad materials and more thorough testing, future studies should examine new hip protectors using nonclustered randomized designs like ours to avoid many methodological biases.

Author Contributions: Dr Kiel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Kiel, Magaziner, Zimmerman, Barton, Birge.
Acquisition of data: Kiel, Magaziner, Zimmerman, Ball, Brown, Stone, Dewkett, Birge.
Analysis and interpretation of data: Kiel, Magaziner, Zimmerman, Barton, Brown, Stone, Dewkett, Birge.
Drafting of the manuscript: Kiel, Magaziner, Zimmerman, Ball, Barton, Brown, Birge.
Critical revision of the manuscript for important intellectual content: Magaziner, Zimmerman, Ball, Barton, Brown, Stone, Dewkett, Birge.
Statistical analysis: Kiel, Zimmerman, Barton.
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Administrative, technical, or material support: Kiel, Magaziner, Zimmerman, Brown, Stone, Dewkett, Birge.
Study supervision: Kiel, Magaziner, Zimmerman, Ball, Brown, Birge.
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