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PREVENTION OF HIP FRACTURE IN ELDERLY PEOPLE WITH USE OF A HIP PROTECTOR

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ABSTRACT

Background Hip fractures are common in frail elderly adults worldwide. We investigated the effect of an anatomically designed external hip protector on the risk of these age-related fractures.

Methods We randomly assigned 1801 ambulatory but frail elderly adults (1409 women and 392 men; mean age, 82 years), in a 1:2 ratio, either to a group that wore a hip protector or to a control group. Fractures of the hip and all other fractures were recorded until the end of the first full month after 62 hip fractures had occurred in the control group. The risk of fracture in the two groups was compared, and in the hip-protector group the risk of fracture was also analyzed according to whether the protector had been in use at the time of a fall.

Results During follow-up, 13 subjects in the hip-protector group had a hip fracture, as compared with 67 subjects in the control group. The respective rates of hip fracture were 21.3 and 46.0 per 1000 person-years (relative hazard in the hip-protector group, 0.4; 95 percent confidence interval, 0.2 to 0.8; $P=0.008$). The risk of pelvic fracture was slightly but not significantly lower in the hip-protector group than in the control group (2 subjects and 12 subjects, respectively, had pelvic fracture) (relative hazard, 0.4; 95 percent confidence interval, 0.1 to 1.8; $P\geq 0.05$). The risk of other fractures was similar in the two groups. In the hip-protector group, four subjects had a hip fracture (among 1034 falls) while wearing the protector, and nine subjects had a hip fracture (among 370 falls) while not wearing the protector (relative hazard, 0.2; 95 percent confidence interval, 0.05 to 0.5; $P=0.002$).

Conclusions The risk of hip fracture can be reduced in frail elderly adults by the use of an anatomically designed external hip protector. (N Engl J Med 2000; 343:1506-13.)

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HIP fractures are a major cause of disability, functional impairment, and death in elderly people.¹⁻⁶ Furthermore, the frequency of hip fractures is likely to increase because the number and mean age of elderly adults are increasing and because, in many countries, the age-adjusted incidence (that is, the average individual risk) of hip fracture is also increasing.^{4,7,8}

The alarming increase in the frequency of hip fracture has resulted in the development of various methods for the prevention of fractures, including exercise, calcium and vitamin D supplementation, specific drugs to prevent or treat osteoporosis, and multifaceted interventions to modify the risk of falling.⁹⁻¹⁵ However, since in most cases of hip fracture the immediate cause of the fracture is a sideways fall with direct impact on the greater trochanter of the proximal femur,¹⁶⁻²⁰ a logical option, but one that has as yet been poorly studied, is to use a device to protect the hips, so that at the time of a fall the force and energy of the impact are attenuated and shunted away from the greater trochanter, preventing fracture.

We undertook this study to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults.

METHODS

Study Design

We studied elderly adults from 22 community-based health care centers in the southern and central parts of Finland. Each center had treatment units (geriatric long-stay facilities or outpatient care units for supported living at home) for the care of elderly people at high risk for hip fracture and other fractures induced by falls.

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Between October 1996 and April 1997, the research coordinator at each health care center, with the help of the other caregivers, selected treatment units for participation in the study and, according to predefined inclusion criteria, identified from each unit all ambulatory men and women who were 70 years old or older and who had at least one easily identifiable risk factor for hip fracture (a previous fall or fracture, impaired balance or mobility, use of walking aids, cognitive impairment, impaired vision, poor nutrition, or a disease or medication known to predispose people to falls and fractures).^{18,21} By definition, persons who were ambulatory were those able to walk, regardless of whether an assistive device (such as a cane or walker) was used or whether another person was needed for support.

When the identification of eligible subjects was finished at a given study center, each of its participating treatment units was randomly designated, in a 1:2 ratio, either as a hip-protector unit (in which all the participating subjects would receive a hip protector) or as a control unit (in which none of the subjects would use a hip protector).²² The randomization was performed according to the treatment unit, and not according to the subject, because the staff members at all the participating centers were convinced that the study could not be conducted successfully if, within a treatment unit, some of the subjects received protectors and others did not, since subjects who did not receive a protector as part of the study might also start to use one. Randomization was performed at the President Urho Kaleva Kekkonen Institute for Health Promotion Research by an independent physician with the use of sealed envelopes.

The calculation of sample size indicated that, if the rate of hip fracture in the hip-protector group was 50 percent lower than the expected rate of fracture in the control group (5 percent per year), we would need to enroll a minimum of 410 subjects in the hip-protector group and 820 subjects in the control group and follow

them for 18 months. However, since the expected rate of hip fracture and the expected reduction in risk were only estimates, we decided that, if necessary, the trial would be continued beyond 18 months, until the end of the first full month after 62 hip fractures had occurred in the control group.

The study protocol was approved by the institutional review board and the ethics committee of the Institute for Health Promotion Research, and all the subjects or their family members or guardians gave written informed consent for participation.

Subjects

We identified 1725 subjects who were eligible for the study according to the inclusion criteria described above; 650 of them were in units that had been assigned to the hip-protector group and 1075 were in units that had been assigned to the control group. After the study had been explained to them, 204 of the subjects in units assigned to the hip-protector group (31 percent) and 94 of the subjects in units assigned to the control group (9 percent) declined to participate; thus, at base line there were 446 subjects in the hip-protector group and 981 subjects in the control group (Fig. 1). The sex and age distributions of the eligible subjects who chose not to participate and of those who did participate were similar.

The dropout rate among these frail elderly adults was expected to be high because of death, onset of an inability to walk, hip fracture, or withdrawal of consent. Therefore, the study positions of subjects who dropped out were to be refilled, whenever possible, by new eligible subjects from a waiting list. Since each treatment unit had its own waiting list, the chance that a new subject would be in the hip-protector group or in the control group was similar to that of any of the subjects in the initial group of 1725 subjects.

A subject who discontinued or reduced the amount of time he or she used the hip protector remained in the study, and follow-up was discontinued only for the reasons given above (death, in-

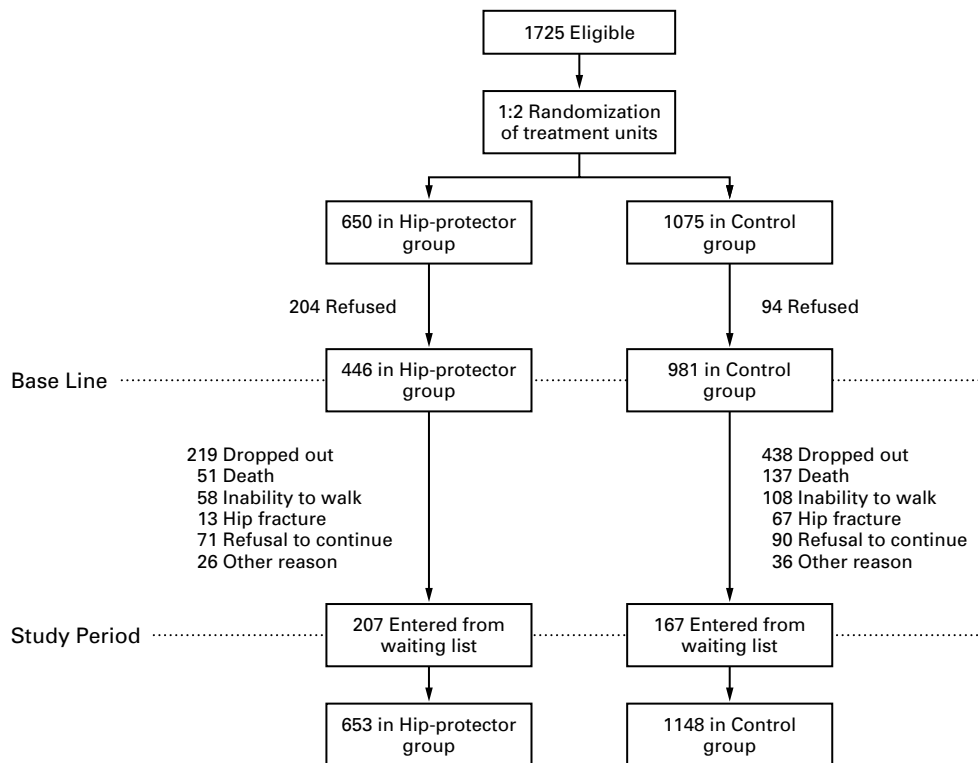


Figure 1. Design of the Study.

ability to walk, hip fracture, or withdrawal of consent). A subject who stopped wearing the hip protector or who reduced the amount of time spent wearing it could, at any time, start wearing it again or increase the amount of time spent wearing it. All the subjects who dropped out of the study were included in the analyses for the period during which they participated.

Hip Protector

The hip protector used (KPH Hip Protector, Respecta, Helsinki, Finland) (Fig. 2) was developed and extensively tested before the initiation of this trial. The tests to which it was subjected included biomechanical tests of its capacity to attenuate force in laboratory models^{23,24} and in young volunteers²⁵ and assessment of its acceptability among nursing-home residents, and users' compliance, during a six-month period.²⁶

The protector shield (length, 19.0 cm; maximal width, 9.0 cm; maximal height, 4.5 cm) is convex, with its deepest portion designed to fit over the greater trochanter, and is shaped to cover the proximal femur. It is anatomically designed to shunt the energy of an impact away from the greater trochanter to the soft tissues anterior, posterior, and superior to the proximal femur and to absorb part of the energy of an impact to the hip. The lowest point of contact of the protector is on the femoral shaft. Two protectors, which are padded, are worn with use of a specially designed, stretchy undergarment containing a pocket on each side for placement of a protector. The design and padding of the hip protectors make them relatively easy to wear under a skirt or pants without limiting walking, sitting, or squatting.²⁶

At each center, the local research coordinator and the other caregivers advised the subjects assigned to the hip-protector group on the use of the device. The subjects in this group were asked to wear the protector whenever they were on their feet and especially when they were at high risk for falling, as when walking on slippery sidewalks in the winter.

Outcome Variables

The primary outcome variable was fracture of the hip or fracture of the proximal femur. All other fractures were also recorded (pelvic fractures, other fractures of the legs or trunk, and fractures of the arms). The fractures were prospectively recorded during the study so that the principal investigators at the Institute for Health Promotion Research were informed about a new fracture as soon as possible after it occurred. In addition, at the end of the study, the research coordinators at each health care center retrospectively reviewed the medical records of the subjects to verify the completeness of the data on any fractures. Each fracture was documented with radiographs. If a subject had more than one fracture other than a hip fracture during the study, he or she continued to participate; only if a hip fracture occurred was follow-up discontinued, according to the stopping rules described above.

Secondary outcome variables were the number and rate of falls in the hip-protector group and the number of days the subjects in this group wore the protector. At the time of a fall, caregivers completed a one-page form with information on the date and place of the fall, the activity being engaged in at the time of the fall, possible reasons for the fall, the circumstances and mechanism of the fall, the height and direction of the fall, the anatomical site of the impact, and injuries, if any. In addition, for subjects in the hip-protector group, whether or not the subject was using the protector at the time of the fall was recorded.

Caregivers used a research diary to mark the days when the subjects in the hip-protector group wore the protector for a minimum of one hour. The total number of days on which the protector was worn was then calculated and expressed as a percentage of all follow-up days.

Statistical Analysis

In the primary analysis, the occurrence of hip fractures was analyzed according to a survival-analysis technique, and the effect of treatment was expressed as a relative hazard and 95 percent confi-

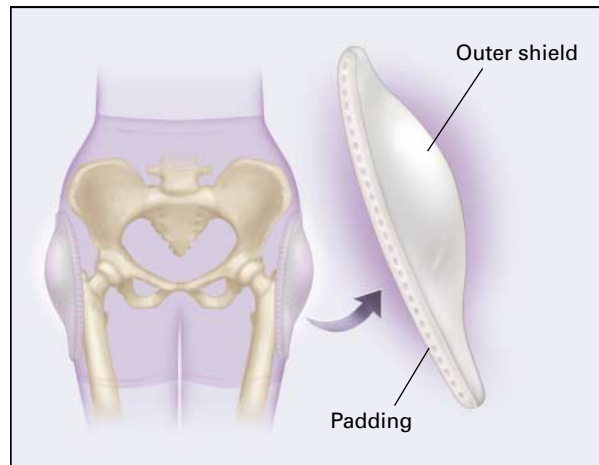


Figure 2. The Hip Protector.

The two padded protectors are worn inside pockets on a stretchy undergarment.

dence interval; the estimate of the relative hazard was then derived by Cox proportional-hazards analysis with use of the likelihood-ratio method.²⁷ The results were then plotted as the cumulative hazard of fracture according to follow-up time. For other fractures, which could be recurrent, Poisson analysis was used.^{28,29} This analysis took into account the possibility of multiple events per person during follow-up, and the results were expressed as a relative hazard and corresponding 95 percent confidence interval.

In the analysis of the efficacy of the hip protector, our goal was to determine the risk of hip fracture (and other fractures) in the hip-protector group when the hip protector was actually worn at the time of a fall, as compared with the risk when the protector was not worn. For this analysis the Poisson method was used. The rates of hip fracture and other fractures were then calculated as the number of fractures per 100 falls and expressed as the relative hazard (and 95 percent confidence interval).

The number of patients who would need to be treated with the hip protector to prevent one hip fracture (the number needed to treat) was calculated as the reciprocal of the absolute difference in the incidence of fracture between the control group and the hip-protector group.^{30,31} The 95 percent confidence limits for the number needed to treat were calculated as the reciprocals of the values that defined the confidence interval for the absolute difference in the incidence of fracture.³²

RESULTS

During the study, 219 subjects in the hip-protector group dropped out of the trial but were included in the analysis for the period during which they participated, and 207 new subjects from the waiting list entered the trial; thus, the analysis included 653 subjects in the hip-protector group (Fig. 1). In the control group, 438 subjects dropped out but were included in the analysis for the period during which they participated, and 167 new subjects entered the trial; thus, there were 1148 subjects in this group. The baseline characteristics of the subjects in the two groups were similar, with a few exceptions (Table 1).

In the hip-protector group, the mean (\pm SD) de-

TABLE 1. BASE-LINE CHARACTERISTICS OF THE SUBJECTS IN THE HIP-PROTECTOR GROUP AND THE CONTROL GROUP.*

CHARACTERISTIC	HIP-PROTECTOR GROUP (N=653)	CONTROL GROUP (N=1148)	P VALUE†
Sex — no. (%)			0.41
Female	504 (77)	905 (79)	
Male	149 (23)	243 (21)	
Age — yr	81±6	82±6	0.006
Height — cm	161.0±8.3	161.4±8.2	0.28
Weight — kg	63.1±11.8	65.5±13.1	<0.001
Body-mass index‡	24.3±3.7	25.1±4.4	<0.001
Type of care — no. (%)			0.15
Geriatric long-stay facility	406 (62)	674 (59)	
Supported home living	247 (38)	474 (41)	
Medical conditions — no. (%)§			
Heart disease	342 (52)	580 (51)	0.46
Dementia	218 (33)	300 (26)	0.001
Hypertension	128 (20)	260 (23)	0.13
Previous stroke, bleeding, or related central nervous system condition	138 (21)	176 (15)	0.002
Diabetes mellitus	114 (17)	230 (20)	0.18
Osteoarthritis	90 (14)	170 (15)	0.55
Rheumatoid arthritis or related condition	46 (7)	83 (7)	0.88
Eye disease (cataract or glaucoma)	47 (7)	80 (7)	0.85
Parkinsonism	43 (7)	55 (5)	0.11
Mental status — no. (%)¶			<0.001
Normal	252 (39)	477 (42)	
Mild impairment	123 (19)	287 (25)	
Moderate impairment	144 (22)	248 (22)	
Severe impairment	134 (21)	135 (12)	
Ability to walk — no. (%)			0.001
Entirely independently	255 (39)	407 (35)	
Independently with an assistive device (cane or walker)	320 (49)	650 (57)	
With help of another person	78 (12)	91 (8)	
Falls during the preceding 12 mo — no. (%)			<0.001
0	287 (44)	578 (50)	
1	89 (14)	180 (16)	
2 or 3	120 (18)	223 (19)	
≥4	157 (24)	167 (15)	
Fractures since the age of 50 yr — no. (%)			0.18
None	462 (71)	846 (74)	
Any	191 (29)	302 (26)	

*Plus-minus values are means ±SD. Because of rounding, not all percentages total 100.

†P values were calculated with use of Student's t-test for continuous variables and the chi-square test for noncontinuous variables.

‡Body-mass index is the weight in kilograms divided by the square of the height in meters.

§Some of the patients had more than one medical condition.

¶Mental status was classified according to the method of Lawton.³³ Data were missing for one subject in the control group.

gree of compliance with use of the protector (i.e., the number of days the protector was worn as a percentage of all available follow-up days) was 48±29 percent (range, <1 to 100). During follow-up, there were 1404 falls in this group, of which 1034 (74 percent) occurred while the hip protector was being used. There were few adverse effects resulting from use of the hip protector; 15 subjects had skin irritation or abrasion, 1 subject reported that the protector caused swelling of the legs, and 1 reported that it caused

bowel irritation. None of the subjects had an allergic skin reaction to the device.

Fractures in the Two Groups

During the study, 13 subjects in the hip-protector group had a hip fracture, as compared with 67 subjects in the control group. The respective rates of hip fracture (per 1000 person-years) were 21.3 and 46.0 (relative hazard of hip fracture in the hip-protector group, 0.4; 95 percent confidence interval, 0.2 to

TABLE 2. FRACTURES DURING FOLLOW-UP IN THE HIP-PROTECTOR GROUP AND THE CONTROL GROUP.

TYPE OF FRACTURE	HIP-PROTECTOR GROUP		CONTROL GROUP		RELATIVE HAZARD (95% CONFIDENCE INTERVAL)*	
	NO. OF FRACTURES	INCIDENCE†	NO. OF FRACTURES	INCIDENCE†	BEFORE ADJUSTMENT	AFTER ADJUSTMENT‡
		no./1000 person-yr		no./1000 person-yr		
Hip fracture	13	21.3	67	46.0	0.4 (0.2–0.8)§	0.4 (0.2–0.8)§
Pelvic fracture	2	3.3	12	8.2	0.4 (0.1–1.8)¶	0.4 (0.1–1.8)¶
Other fracture of the legs or trunk	13	21.3	30	20.6	1.0 (0.5–2.0)¶	1.3 (0.6–2.6)¶
Fracture of the arms**	10	16.4	29	19.9	0.8 (0.4–1.7)¶	0.7 (0.3–1.5)¶

*The relative hazard of hip fracture was calculated by Cox proportional-hazards analysis; the relative hazard of other fractures was calculated by Poisson analysis.

†The total follow-up time was 611 person-years in the hip-protector group and 1458 person-years in the control group.

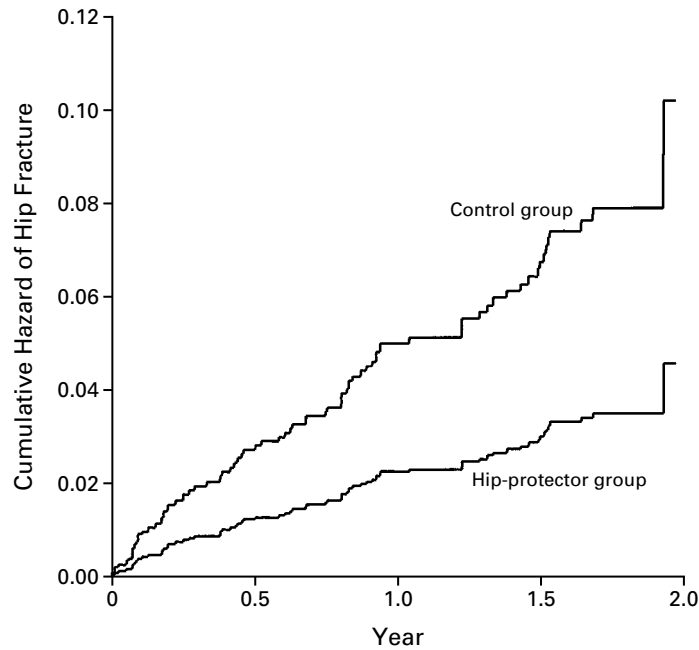
‡Relative hazards were adjusted for sex, age, body-mass index, mental status, ability to walk, previous falls, and previous fractures.

§P=0.008 for the comparison between the hip-protector group and the control group.

¶P≥0.05 for the comparison between the hip-protector group and the control group.

||One person in each group had two fractures of the legs or trunk.

**In the control group, two persons had two arm fractures each.



No. OF SUBJECTS AT RISK

Hip-protector group	653	449	297	155	6
Control group	1148	994	769	543	31

Figure 3. Cumulative Hazard of Hip Fracture in the Hip-Protector Group and in the Control Group.

TABLE 3. FRACTURES IN THE HIP-PROTECTOR GROUP, ACCORDING TO USE OF THE PROTECTOR.

TYPE OF FRACTURE	FALLS WITH THE HIP PROTECTOR		FALLS WITHOUT THE HIP PROTECTOR		RELATIVE HAZARD (95% CONFIDENCE INTERVAL)*	
	NO. OF FRACTURES	INCIDENCE†	NO. OF FRACTURES	INCIDENCE†	BEFORE ADJUSTMENT	AFTER ADJUSTMENT‡
	no./100 falls		no./100 falls			
Hip fracture	4	0.39	9	2.43	0.2 (0.05–0.5)§	0.1 (0.03–0.5)¶
Pelvic fracture	1	0.10	1	0.27	0.4 (0.02–5.7)	0.3 (0.02–6.6)
Other fracture of the legs or trunk	6	0.58	7	1.89	0.3 (0.1–0.9)**	0.4 (0.1–1.5)
Fracture of the arms	7	0.68	3	0.81	0.8 (0.2–3.2)	1.8 (0.3–9.2)

*The relative hazard of fracture was calculated by Poisson analysis.

†There were 1034 falls while the hip protector was being worn, and 370 while it was not being worn.

‡Relative hazards were adjusted for sex, age, body-mass index, mental status, ability to walk, previous falls, and previous fractures.

§P=0.002 for the comparison between falls with the hip protector and falls without it.

¶P=0.003 for the comparison between falls with the hip protector and falls without it.

||P≥0.05 for the comparison between falls with the hip protector and falls without it.

**P=0.03 for the comparison between falls with the hip protector and falls without it.

0.8; P=0.008) (Table 2 and Fig. 3). Two subjects in the hip-protector group had pelvic fractures, as compared with 12 subjects in the control group; the respective incidence rates were 3.3 and 8.2 per 1000 person-years (relative hazard of pelvic fracture in the hip-protector group, 0.4; 95 percent confidence interval, 0.1 to 1.8; P≥0.05). The risk of other fractures was similar in the two groups (Table 2). Adjustment of the results for potentially confounding variables did not alter the findings.

Fractures in the Hip-Protector Group According to Use of the Protector

Four subjects in the hip-protector group had hip fractures (among 1034 falls) while wearing the hip protector (0.39 fracture per 100 falls), whereas nine subjects in this group had hip fractures (among 370 falls) while not wearing the hip protector (2.43 fractures per 100 falls). The relative hazard of hip fracture while wearing the device was 0.2 (95 percent confidence interval, 0.05 to 0.5; P=0.002) (Table 3).

The risk of pelvic fracture or fracture in the legs or trunk also seemed to be related to the use of the hip protector at the time of the fall, whereas the risk of fracture of the arms was not (Table 3).

Number Needed to Treat

According to the comparison of the hip-protector group with the control group, the number needed to treat for one year to prevent one hip fracture was 41 persons (95 percent confidence interval, 25 to 115), and the number needed to treat for five years was 8 persons (95 percent confidence interval, 5 to 23).

DISCUSSION

The results of our trial indicate that among ambulatory elderly adults who are at an increased risk for hip fracture, the risk of fracture can be reduced by 60 percent by the use of an anatomically designed external hip protector. In accordance with this observation, the risk of fracture can be decreased by more than 80 percent if the protector is worn at the time of a fall.

This trial had several strengths. In addition to being randomized, the trial was large enough to fulfill the calculated requirements for statistical power. The biomechanical capacity of the hip protector for force attenuation²³⁻²⁵ and the compliance among persons offered the protector²⁶ were well documented before the trial. These features are probably important reasons why the protector was efficacious and was used successfully by the subjects in this study (74 percent of the falls in the hip-protector group occurred while the subjects were wearing the protector). This, in turn, allowed us not only to compare the risk of hip fracture in the hip-protector group with that in the control group but also to assess the biomechanical efficacy of the protector in actual falls.

The chief weakness of the study was that not all of the subjects were willing to wear the hip protector as a part of their daily clothing. In our trial, 31 percent of the eligible subjects refused to wear the protector and thus remained without protection. This naturally limits the extent to which the results of our study can be generalized to all elderly persons. On the other hand, in no study of fracture prevention has the intervention been acceptable to all subjects, and in our

study 9 percent of the subjects assigned to the control group also refused participation, a sign of the unwillingness of some frail elderly people to participate in any type of follow-up.

In this trial, randomization was performed according to treatment unit at the participating centers rather than according to individual subject. This technique ordinarily requires allowance in the analysis for a cluster effect (i.e., correlation among the responses within a unit). However, since the events we analyzed (fractures) were rare, the within-unit correlation is likely to have had little effect on the results.

The design of the study resulted in a difference in the rates at which the subjects in the two groups initially refused to participate (31 percent in the hip-protector group and 9 percent in the control group) — an important potential source of selection bias. However, we think that the probability of this bias is not very high, because the age and sex distribution of the subjects who did participate in the hip-protector group or the control group was similar to that of the subjects who chose not to participate. Moreover, the other base-line characteristics of the subjects in the two groups were similar, which suggests that their participation was unbiased.

In this study, the risk of pelvic fracture was slightly but not significantly lower among the subjects in the hip-protector group than among those in the control group. This result is not surprising, because a pelvic fracture, like a hip fracture, is likely to occur as a result of a fall,^{25,34} and the protector may be able to prevent the pelvic fracture by partially absorbing and spreading the energy of impact. The finding that the rate of other fractures was not lower in the hip-protector group than in the control group is also not surprising and suggests that subjects in the hip-protector group were not more attentive than their counterparts to the risks of falling and fractures overall. Protective devices designed specifically for other parts of the body will need to be developed if protector-based prevention against other fractures is desired.

The compliance of the frail elderly adults in our study with use of the hip protector was in line with that in a preliminary study.²⁶ By intention, in both of these studies, the primary investigators never came to the treatment units; the local caregivers independently took care of the subjects (and the hip protectors). This practical approach should approximate the real-life conditions of most geriatric health care units.

We conclude that the risk of hip fracture can be reduced in frail elderly adults through the use of an anatomically designed external hip protector. Only 41 persons need to use the protector for one year (or 8 persons, for five years) in order for one fracture to be prevented.

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