Mechanical and Compliance Study of a Modified Hip Protector for Old Age Home Residents in Hong Kong

SZE Pan Ching

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Thesis/Assessment Committee

Professor Leung-kim HUNG (Chair)

Professor Kwok-sui LEUNG (Thesis Supervisor)

Professor Lin QIN (Committee Member)

Professor Arthur Fuk-tak MAK (External Examinar)

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秦嶺教授 (委員)

麥福達教授 (校外委員)

ABSTRACT

Abstract of thesis entitled:

Hip protectors (HP) can be an important strategy in prevention of hip fractures, particularly in Chinese where the population is aging and hip fracture incidence is increasing. However, there is no commercially available HP for Chinese elderly while overseas products are manufactured based on western anthropometric database. Previous studies also showed that poor compliance is the major obstacle for the effectiveness of HP in prevention of hip fracture. However, there was no previous attempt in investigating the factors associated with HP compliance among Chinese elderly. Therefore, the objectives of this study are (1) to develop a HP which is of sound force attenuation properties and suitable for Chinese elderly; (2) to evaluate the acceptance and compliance rate of the HP among the Chinese elderly; and (3) to investigate the determinants of compliance and non-compliance of HP.

A modified HP was successfully developed with 50% smaller in size when compared to western designs to reduce bulkiness. Silicon padding was also added to improve comfort. Anthropometric consideration was made to fit the body figure of the local population. Fabric material with good properties of moisture absorbance and air permeability was specially selected for making the pants in order to suit the subtropical weather in Hong Kong. The force attenuation property of the HP was evaluated by mechanical testing in fall-simulated drop-weight settings with and without the presence of the HP. Clinically, 179 ambulant female residents aged 70 or above were recruited from four local elderly hostels in the New Territories and Kowloon for this compliance study of the modified HP. Compliance rate was recorded by hostel staff in unannounced checks as scheduled by the investigators for a one-year

period.

The impact force in mechanical testing was significantly lower ($p<0.001$) with the application of HP, and was found to be significantly lower than the fracture threshold of proximal femur of old ladies (3100N, $p<0.001$). There were 66% of subjects accepted to wear HP with the average compliance rate was only averaged 40.4% (night 40.1%, day 40.6%) across the study period. Experiencing the HP as comfortable to wear and gaining of confidence against fall were the most determining factors of compliance ($p<0.001$). The major reasons for non-compliance were tightness ($p<0.001$) and feeling of too hot to wear ($p=0.02$). Compliance at the hostel with the highest staff-to-subject ratio was 48% compared to 28% of that with the lowest ratio though the difference was not significant ($p=0.29$). There was no significant association between subject's characteristics and compliance. No subject sustained hip fractures while wearing the HP compared with 2 occurred without wearing HP during the study period. The confidence against fall was also increased after wearing hip protector ($p=0.01$)

The HP acceptance and compliance rate was comparable to and even better than that of some foreign studies (19% – 57%), especially the night time compliance. Determinants of compliance were mainly related to the feedbacks of subjects after using HP rather than the characteristics of subjects. Being too hot in Hong Kong and the necessary tightness of the pants were the major obstacles in using HP. The effect of these factors might be so large that other possible determinants related to subjects' characteristics may be masked. The modified HP was found to be effective to attenuate the impact force in laboratory study. No hip fracture was observed while HP

was being worn, though its effectiveness needs a larger controlled study to justify.

In order to further improve the compliance, a design of HP without pants is recommended in the future. Education program should also be reinforced to facilitate the acceptance and compliance of hip protector. Hip protector should also be provided to people with high risk of fall and fracture in order to improve its effectiveness.

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摘要

論文摘要：

髖部保護器（Hip protectors，HP）可作爲預防髖部骨折的一項重要措施，尤其是對老齡化日趨嚴重、髖部骨折發生率逐步提高的中國婦女。然而，目前市場上並沒有適合中國老年人的髖部保護器，絕大多數進口產品均是按照西方的人體工學特徵所製造的。研究表明，差強人意的使用依從率是影響髖部保護器效果的最大的不利因素，但在本研究之前，並沒有針對中國老年人髖部保護器使用依從率相關因素的研究。因此，本研究旨在：（1）開發一種具有顯著的力學衰減效果，並且適用於中國老年人的髖部保護器；（2）測量中國老年人對髖部保護器的接受程度和使用依從率；（3）分析影響髖部保護器使用依從率的決定性因素。

本研究成功開發了一種較西方設計在體積上縮小了 50%的改良型髖部保護器，其避免了髖部保護器臃腫的外形，並增加了矽膠墊以提高舒適性。人體工學設計參照本地老年人群的人體測量資料，織物採用吸汗及透氣性極佳的材料以適應香港的氣候環境。保護器的力學衰減效果採用重物落體-類比摔倒的力學儀器進行測試。臨床方面，新界及九龍地區老年中心的 179 名 70 歲或以上具有行走能力的女性受試者參與了改良型髖部保護器使用依從率的調查研究，在爲期一年的研究中，老年中心員工按照研究計畫以不告知的方式記錄了髖部保護器的使用依從率。

力學測試顯示，在使用髖部保護器的情況下，應力顯著降低（$p<0.001$），並且明顯低於老年女性股骨近端骨折的應力閾值（3100 牛頓, $p<0.001$）。臨床調查研究中，66%的受試者願意穿著髖部保護器，但平均使用依從率僅爲 40.4%（晚間 40.1%，日間 40.6%）。影響使用依從率的決定性因素包括髖部保護器穿著的舒適性以及對預防跌倒的信心（$p<0.001$）。導致不依從的主要原因爲緊束感

（p<0.001）和悶熱感（p=0.02）。在員工-受試者比例最高的老年中心，保護器使用依從率爲 48%，在比例最低的老年中心則爲 28%，但並無顯著差異（p=0.29）。受試者的性格特徵與使用依從率不相關。調查過程中，穿著髖部保護器的受試者沒有發生髖部骨折，而未穿著保護器的受試者中有 2 例發生額髖部骨折。受試者穿著保護器後對於預防跌倒的信心顯著提高（p=0.01）。

本研究中，髖部保護器在接受程度和使用依從率方面相當於或高於國外研究（19% – 57%），晚間使用依從率尤爲明顯。使用依從率的決定性因素主要爲受試者使用保護器後的回饋而非性格特徵，其中香港炎熱的氣候及必要的緊束感是影響使用依從率的主要因素。這些因素的影響非常顯著，有可能掩蓋了受試者性格對使用依從率的影響。實驗室研究中，改良型髖部保護器具有良好的應力衰減效果。臨床調查研究中，穿著髖部保護器的受試者未出現髖部骨折，但其效果需要更大規模的對照試驗以進一步證實。

爲提高使用依從率，新型的不含短褲的髖部保護器是未來的研究方向。同時應加強針對髖部保護器使用的教學課程以提高髖部保護器的接受程度及使用依從率。在跌倒和骨折的高風險人群中推廣髖部保護器可增加其有效性。

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LIST OF ABBREVIATIONS

ABC	Activities-specific Balance Confidence scale
ANOVA	Analysis of variance
EH	Elderly hostel
HP	Hip protector
MBI	Modified Barthel Index
MMSE	Mini-mental State Examination
NHPT	Nine-hole-peg test
SD	Standard deviation
SPSS	Statistical Package for Social Science
TUG	Time up and go test

LIST OF DEFINITIONS OF TERMS

Acceptance	Percentage of subject accept to wear hip protector, equals to the no. of subjects accept to wear hip protector over the total no. of subjects recruited
Compliance	Percentage of time among the subjects who accept to wear hip protector actually wear hip protector during the study period, equals to the no. of episodes of checking in which hip protector was being worn over the total no. of episodes of checking
Incidence of protected fall	No. of protected falls over the product of compliance and no. of subjects who accept to wear hip protector during the 12 months study period, express in no. of falls per person year
Incidence of unprotected fall	No. of unprotected falls over the product of one minus compliance and no. of subjects who accept to wear hip protector during the 12 months study period, express in no. of falls per person year
Percentage of protected fall	No. of falls occur while hip protector was being worn over the total no. of falls within the study period
Protected fall	Falls occur while hip protector is being worn
Unprotected fall	Falls occur while hip protector is not being worn

Introduction

I. INTRODUCTION

1.1 Epidemiology of hip fracture among elderly worldwide

Population aging has become a worldwide challenge to the society, particularly the medical system. There are totally 88 million people with age over 65 in China, which accounts for 7% of the total population (China 5th population census, 2000). Population aging is even more serious in developed regions or countries. In 2001, there was 0.85 million elderly in Hong Kong, which accounted for about 12.2% of the total population (Census and Statistics Department of Hong Kong, 2005). With the general increase in life expectancy and decrease in birth rate, it is estimated that the number of elderly will increase dramatically to 25% of the total population in year 2031. Medical problem is one of the major concerns of population aging as a result of general deterioration in health among elderly. Among the medical problems, hip fracture is one of the most common and serious ones.

Hip fracture among elderly has become a global concern. In 1990, there were about 1.66 million hip fractures among the elderly worldwide (Cooper et al. 1992). The incidence of hip fractures among the whole population, in terms of fracture rate per 100,000 people, varied between 45.4 for male and 39.6 for female in Beijing to 141.3 for male and 274.1 for female in Reykjavik in Iceland as reported from a cross-national report involving nine countries or areas in different places of the world (Schwartz et al. 1999). The incidence of hip fractures increases with age. Studies on elderly population revealed much higher incidence of hip fracture than that of the general population. A study in Cardiff, UK showed that the incidence rate of hip fractures among elderly people was as high as 770 per 100,000 population per year,

while people living in care homes would have much higher incidence of 4,950 per 100,000 population per year (Brennan nee Saunders et al. 2003). Another study in New Zealand also showed similar findings with hip fracture incidence rate of 790/100,000 among females and 360/100,000 among males (Norton et al. 1997). In Hong Kong, there were 4000 hip fracture cases per year and gave a crude estimation of hip fracture incidence of 500/100,000 and 1100/100,000 population for male and female respectively for the elderly (Chan et al. 2004, Lau et al. 1999). Clearly, hip fracture has become a global problem and its incidence is expected to increase dramatically in the next 50 years. It was projected that there will be 6.26 million hip fracture cases worldwide by the year 2050 (Cooper et al. 1992). Although this projection did not take the modern developing strategies for prevention of hip fractures into account, it is still anticipated that there will be 1-3% annual increase in the hip fracture incidence in most areas in the world (McColl et al. 1998, Koeck et al. 2001, Cummings and Melton 2002). The lifetime risk of hip fractures at the age of 50 is also as high as 11.1% and 22.7% for male and female respectively (Oden et al. 1998).

In the past decade, countries like European countries and America with predominantly Caucasian population account for about half of the hip fracture cases in the world, while Asian countries only account for about one quarter (Gullberg et al. 1997), although the total population in Asian countries accounts for about half the global population. However, it was estimated that hip fracture cases in Asian will increase dramatically in the next 50 years and will account for half of the total hip fracture cases in 2050 (Gullberg et al. 1997). The major reason for this is the major demographic changes in the coming 5 decades will occur in Asian countries. The

elderly population in Asia will increase two fold by the year 2050 as a result of increasing life expectancy due to the advancement of medical technology and welfare systems in those developing countries. Although the incidence of hip fractures in two Asian areas (Shenyang, China and Kaohsiung, Taiwan) are still lower than that in America or Northern Europe (Yan et al. 1999, Huang et al. 2000), there are trend for increasing the incidence in Asia. Actually, from a recently published study in Japan, the numbers of hip fractures increased 1.4 times in the past decade (Yoshimura et al. 2005). Another study also found that the hip fracture incidence rate in four Asian countries, especially the urbanized area, were comparable to that of the America, and which will be a major public health challenge in Asia (Lau et al. 2001). Clearly, hip fractures cases increase dramatically as a result of population aging, and it is particularly serious in areas with rapid increase of the number of elderly people like Asia. It is alarming that more attention is need towards the problems of hip fractures in these areas.

1.2 Impact of hip fractures

Hip fracture is a big problem among the elderly people, not only because its commonness, but also its serious consequences. It is life threatening. It can also bring great adverse impact to the elderly people's health as well as to the society. There were 1.75 million disability adjusted life-years lost, representing 0.1% of the global burden of disease world-wide and 1.4% of the burden amongst women from the established market economies (Johnell et al. 2004).

1.2.1 Mortality

Although the advancement in surgical and anesthetic techniques which lowers

the mortality rate of hip fracture, the in-hospital mortality is still 6.3% (Jiang et al. 2005). It increases to 8% in the first three months and 17% to 30.8% in the first year following the hip fracture (Center et al. 1999, Cree et al. 2000, Magaziner et al. 2000, Jiang et al. 2005). It could be even higher in some specific groups such as male gender, older age and with more pre-fracture comorbidities (Cree et al. 2000, Jiang et al. 2005). There were 740,000 deaths estimated to be associated with hip fracture (Johnell and Kanis 2004).

1.2.2 Hospitalization and institutionalization

Apart from mortality, another adverse outcome of hip fractures among the survivors is prolonged hospitalization and increased risk of institutionalization. Nearly all elderly with hip fractures need to be hospitalized. In Hong Kong, hip fracture cases occupy 150,000 hospital bed day each year, which is the forth major reason for hospital bed occupancy (Ho and Chan 2003). An average length of stay in acute hospital of the hip fracture cases is 7 days in Hong Kong (Chan et al. 2004). Nearly half of hip fracture cases could not go back to their original accommodation (van Balen et al. 2001), and in which 20% of the cases will be institutionalized and account for a total number of 140,000 nursing home admission in the America (Melton 2003). The risk of institutionalization or death following hip fractures could also be nearly seven times higher than people without hip fracture (Fransen et al. 2002).

1.2.3 Morbidity

Hip fracture often associates with impairments in physical function. Mobility is one of the most impaired function following hip fracture, more than half of the independent walker could not ambulate independently after hip fracture (Cummings

and Melton 2002). There are 60% of the hip fracture cases having difficulties with at least one essential activities of daily living (ADL) and 80% are restricted in other activities (Cooper et al. 1997). Additional dependency was observed in functions of ADL particularly for those requiring predominant lower extremity functioning such as climbing stairs, getting in or out of bath/shower and getting on or off the toilet when compared with the pre-fracture functioning (Magaziner et al. 2000, Lin et al. 2004). This additional dependency even persists after 2 years following the hip fracture (Magaziner et al. 2000). Actually, only 17% of hip fracture cases achieve the same level of ADL as before fracture (van Balen et al. 2001). These impairments associated with hip fracture are the major obstacles for early hospital discharge and reintegration into social life. They can also be a reason for increased risk of institutionalization following hip fractures.

1.2.4 Psychological impact and quality of life

Morbidity associate with hip fractures often brings further impact to the self perceived health and psychological impact to the elderly, and in addition to the physical impairments, which in turns lead to deterioration in quality of life. Elderly with hip fracture is generally with poorer self-perceived health as a result of pain and complications after hip fracture (Borgquist et al. 1992). Psychological impact was also a major problem to bring fears and poor fall-related self efficacy to people with hip fractures (Petrella et al. 2000), which lead to avoidance of activities and even poorer functioning (Tinetti et al. 1994b). The combination of these effects will lead to deterioration in individual's health and functioning, and therefore it is not unusual to see the impact of hip fracture on quality of life (Hall et al. 2000, Randell et al. 2000, van Balen et al. 2001). The quality of life of people with hip fracture was found to be

significantly lower than people without hip fracture in all domains including physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health (Hall et al. 2000). The decreased physical function after hip fracture result in restrict social activities, increased social isolation, and contribute to lower self-esteem and hence poorer perception of body image, also account for the deterioration in the domains including physical function, social activity and general health (Randell et al. 2000).

1.2.5 Financial burden

Hip fracture also brings great impact to the health care system, in terms of financial burden and burden of care. The cost for each hip fracture case, including medical expenditure in acute phase and the expenditure associated with the medical follow up and pharmacy cost in the subsequent year range from around US$8,000 to 22,000 in Europe and North America (Brainsky et al. 1997, Diamond et al. 1997, Gullberg et al. 1997, Zethraeus et al. 1997, Laet et al. 1999, Koeck et al. 2001, Wiktorowicz et al. 2001). The cost could be doubled for cases if long term care is needed (Wiktorowicz et al. 2001). The financial impact of hip fractures that brings to the health care systems can be seen in the figures of total medical expenditure in different countries: UK, 900 million pounds (Dolan and Torgerson 1998); Australia, AUD$420 million (Diamond et al. 1997), USA, US$20 billion (Braithwaite et al. 2003); Canada, CAD$750 million (Wiktorowicz et al. 2001) and Hong Kong, HK$150 million (Lau and Woo 1998).

1.3 Causes of Hip Fracture

Hip fracture (Figure 1.1) refers to a fracture of the femur in the area of bone

immediately distal to the articular cartilage of the hip, to a level of about five centimeters below the lower border of the lesser trochanter (Parker et al. 2005). It can be a fracture occurs at the femoral head, at the neck of femur, inter-trochanteric region as well as at the sub-trochanteric region (Leung 2001). Most of the hip fractures are inter-trochanteric, which accounts for about half the hip fractures (Michelson et al. 1995) and is more often to be found in people with older age (Fox et al. 2000).

1.3.1 Mechanisms of hip fracture

The causes of hip fracture are multifactorial. A number of factors like decreased hip bone mineral density (BMD), muscle atrophy, cognitive impairment and impaired visual function can contribute to the occurrence of hip fractures (Marks et al. 2003). The most direct cause of hip fracture is, however, fall. Fall contributed to over 90% of hip fracture (Grisso et al. 1994). Particularly, when the fall occurs as a side fall, in which the impact is directly acted on the greater trochanter, and with a force exceeding the fracture threshold of the proximal femur, hip fracture occurs. Hayes and co workers showed that an impact at the hip or at the lateral side of legs could increase the risk of hip fractures up to 20 times among the nursing home fallers (Hayes et al. 1993). Also, the potential energy associated with fall also correlates positively with the risk of hip fracture (Greenspan et al. 1994). This also explain that taller people have higher risk of hip fracture (Greenspan et al. 1998), as the impact energy, which is transferred from potential energy, is on positive scale with the falling height of the person. Therefore, the risk of hip fracture depends on falling height and falling mechanism.

1.3.2 Degenerated protective mechanism

Another factor that contributes to the causes of hip fracture is delayed or degenerated protective mechanism. This mechanism protects the body from falling down when there is disturbance of the centre of gravity of the body through controlled and reflexive sensory-motor function. Therefore, good perceptual functioning as well as muscle strength are the key issues to prevent falls, which may eventually result in fractures. Actually, it was shown that disturbance in balance among elderly as a result of age-associated decline in proprioception, vestibular function and vision can contribute to increased risk of fall and associated hip fractures (Luukinen et al. 1997, Boonen et al. 1999, Ivers et al. 2000).

Apart from balance, muscle strength also plays the crucial role in the protective mechanism. Muscle weakness, as a result of decrease in muscle mass and particularly age-related declined in muscle power associates positively with risk of hip fracture (Luukinen et al. 1997, Philips et al. 1998). Farmer and co-workers also suggested that low arm muscle area might slow normal protective reflex, such as forearm extension to provide protection to the body in the occasion of fall (Farmer et al. 1989). Similarly, people with weaker knee extensor, which plays the crucial role in prevention of falling, will have increased risk of hip fractures (Sherrington et al. 1998). Luukinen and co-workers further explained this by showing that weaker knee extensors slowed the protective reflex of knee extension as well as increased the falling velocity to give a higher chance of hip fractures (Luukinen et al. 1997). This also explains the findings that people have difficulties in rising from a chair without using hands to support are at higher chance of hip fractures (Cummings et al. 1995, Bensen et al. 2005). The age-related declined in muscle performance in arm and hip will slow the protective

response so as to increase risk of hip fracture with age. Actually in a recent muscle biopsy study, it was found that the composition of muscle fiber changed significantly with age, particularly the composition of muscle fibre type II a, which plays the crucial role in providing the necessary protective response, decrease significantly with age (Lee et al. 2005). This also explains why the risk of hip fracture increase drastically with age from a local population based study on the fractures among elderly people (Lam et al. 2005).

1.3.3 Poor hip strength indices

For a fracture occurs, there should be an impact force with a magnitude greater than that of the bone could sustain. Therefore, apart from factors associated with the magnitude of the impact force such as fall direction, fall height, velocity of impact etc, the magnitude of the breaking threshold of the bone and the magnitude of the energy that the localized shock absorber such as soft tissue, muscle etc. could absorbed also play the crucial role in determining the chance of fracture. Thus BMD, which is one of the parameters contributed to bone strength, is widely studied on its association with hip fractures. Loss in BMD has already been shown to be a risk factor of hip fracture (Nguyen TV et al. 2005). However, it seems that only the BMD of the femoral neck shows significant correlation in the risk of hip fractures, especially for fractures at the neck of femur, while BMD of other parts of the proximal femur, such as the trochanteric area, only shows limited predictive value of hip fracture (Greenspan et al. 1998, Fox et al. 2000, Johnell et al. 2005, Nguyen ND et al. 2005). Nguyen and co-workers found that for each standard deviation reduction in femoral neck BMD, the risk of hip fracture increases by 3.6 fold in women and 3.4 fold in men (Nguyen ND et al. 2005). Johnell and co-workers had similar findings in the

increasing risk of hip fractures in association with femoral neck BMD decrease (Johnell et al. 2005). However, these associations are only found to be strong in people with comparatively younger age, say between 50 to 70 (Greenspan et al. 1994, Fox et al. 2000). In contrast, for people with older age, trochanteric fractures are in dominance and BMD seems to be less predictive (Fox et al. 2000). Actually, osteoporosis could only be found in about half of the hip fractures case (Seeman and Eisman 2004), and there could be some other associated factors. Ahlborg and his colleagues in a recent research found that other hip strength indices, such as the femoral neck diameter and the cross-sectional moment of inertia, in addition to femoral neck BMD, was strongly associated with risk of hip fracture (Ahlborg et al. 2005). Other structural factors like hip axis length could also be the risk factor of hip fractures regardless of age and gender (Frisoli et al. 2005).

1.4 Prevention of hip fractures

As the two major causes of hip fractures are fall and poor bone strength, prevention of fall and improvement of bone strength are the two major strategies to prevent hip fractures.

1.4.1 Reduction the chance of lateral fall

Prevention of lateral fall is the most direct strategy to prevent hip fractures as hip fractures seldom occur without fall. Strategies on prevention of fall have been widely studied. The causes of fall can be both intrinsic and extrinsic. Intrinsic factors such as poor balance and muscle strength as a result of age-associated degeneration or deterioration after medical diseases such as stroke or Parkinson's disease, poly-pharmacy, visual deficit and syncope have proven to be risk factors of fall

(Tinetti et al. 1988, Berg et al. 1997, American Geriatrics Society et al. 2001). On the other hand, extrinsic factors like environmental hazards and improper shoe ware give additional risk of fall (Lord and Bashford 1996, Cumming et al. 1999). Therefore, intervention strategies targeting on both the intrinsic factors and extrinsic factors of fall were investigated. Individually targeted exercise programs including progressive muscle strengthening, balance training and walking plan are effective in reducing up to 30% of fall incidence and 37% of fall related injuries among community-dwelling elderly (Campbell et al. 1997; Campbell et al. 1999a; Robertson et al. 2001). Wolf and co-workers also showed the effectiveness of Tai Chi on reducing up to 33% of fall (Wolf et al. 1996). However, these programs are not effective in prevention of fall among elderly requiring institutional care (Mulrow et al. 1994, Donald et al. 2000). Intervention strategies targeting on other intrinsic factors such as referral for visual correction and medication withdrawal also shows evidence on reducing falls when applies together with other programs like home safety and exercise intervention but not on themselves alone (Campbell et al. 1999b, Day et al. 2002). For extrinsic strategies, it is also demonstrated that modification of environmental hazard can effectively reduce fall incidence, and was particularly effective for people with history of fall (Cumming et al. 1999; Pardessus et al. 2002, Nikolaus et al. 2003). There are also increasing evidence on applying multifactorial intervention programs on targeted groups with high risk of fall in reducing fall incidence (Tinetti et al. 1994a, Close et al. 1999, van Haastregt et al. 2000, Kingston et al. 2001, Lightbody et al. 2002).

1.4.2 Increase hip strength indices

Another approach to prevent hip fracture is to increase the hip strength indices so that even when a fall occurs, the chance of fracturing the hip will be less. Among the

hip strength indices, BMD is one of the indices with potential to improve. In fact, there are a number of studies investigating the effect of applying pharmaceuticals on improvement of BMD and hence the prevention of osteoporotic fractures (Stevenson et al. 2005). Studies showed that prescribing bisphosphonates to people with osteoporosis could reduce their chance of hip fracture by up to 50% across a spectrum of age and different groups of patients including those with cognitive impairments (Hochberg et al. 2005, Sato et al. 2005). A recent research also demonstrate the effect of raloxifene not only on increasing BMD, but also on achieving structural change of proximal femur by increasing diameter of the femoral neck, intertrochanteric region and proximal shaft of femur which in turn increase its resistance to axial and bending stresses, which are the key parameters in determining fracture threshold (Uusi-Rasi et al. 2006). Newer drugs like strontium ranelate is also proven to be effective to reduce both vertebral and non-vertebral fractures and with minimum side effects (Reginster et al. 2006). Research studies also showed that these pharmacological stragegies are cost-effective in prevention of fractures among people with low BMD (Fleurence et al. 2006).

1.4.3 Limitations of current strategies

Although the effectiveness of various strategies on prevention of fall are widely researched, there is only very limited evidence of their effects on prevention of fall-related injuries (Gillespie et al. 2004), and also little is known about their effect on prevention of hip fractures. On the other hand, improvement of BMD seems to be an effective method to prevent hip fracture, however, the major limitation for these pharmaceutical approach is it needs long time to see the effect. Most drugs needs more than 2 years time to achieve the increase in BMD and reduce fracture rate

(Papapoulos et al. 2005), and by the time, a number of fractures will have occurred. Therefore, strategies which are both effective and efficient are important in prevention of hip fractures.

1.5 Hip protectors for prevention of hip fractures

The use of hip protectors for prevention of hip fracture has been widely researched in the past decade (Parker et al. 2005). Hip protectors are external protective device to protect the hip from fracture in the occasion of fall. If people cannot break the fall with his protective mechanism as he loses balance, a fall occurs. If people fall laterally and land with their hip, the impact will be directly on the hip, and probably fracture their hip if the impact is greater than the amount that their hip can sustain without fracture. Therefore, previous strategies on prevention of hip fractures is firstly to prevent or break the fall, and secondly to improve the bone strength. However, the majority of falls cannot be prevented and only about 30% to 40% of falls are preventable (Gillespie et al. 2003). On the other hand, improvement of bone strength can significantly reduce the risk of hip fracture but it takes years to achieve the effect (Papapoulos et al. 2005). Therefore, a third approach is developed by providing site-specific protection. The mechanism of protection provided by hip protector is to attenuate the impact force to the hip when fall occurs. Thus even when a fall occurs, the hip protector will be able to provide instant protection to the hip so that the chance of hip fracture will be lower for people who wear hip protector than those who do not.

There were many types of hip protectors developed in the past decade. Most of the hip protectors consist of two parts: the protective pads and the specially designed

underwear. The protective pads provide the force attenuation properties, which is usually made of different kinds of plastics or foams. The specially designed underwear, usually with pockets, is for holding the pads in position so that when people wear them, the pads cover the lateral side of hip at the trochanteric area.

1.6 Effectiveness of hip protector

Effectiveness of hip protectors have been studied in a wide range of categories including laboratory studies on force attenuation, clinical study on hip fracture prevention as well as the cost-effectiveness studies.

1.6.1 Laboratory studies on effectiveness in force attenuation

The most important property of hip protectors is its force attenuation power, that is whether it can sufficiently reduce the impact force to a safety level, which is significantly below the fracture threshold of the proximal femur of the elderly. The force attenuation power of hip protectors depends on their mechanism of protection. Although there are many types of hip protectors, their mechanism of protection can be categorized to either energy absorption or energy shunting. Energy absorption pads are usually made of foams or other energy absorption materials, which absorb part of the energy during fall so that the energy transmits to the trochanter become less. On the other hand, energy shunting pads are usually made of harder materials like plastics which shunt the energy away from the trochanteric area. Thus the energy shunting pads are usually in oval shape with a convex area at the middle of the pads so that the trochanteric area is free from contact with pads, and energy will be shunted to the surrounding parts to avoid direct transmission of energy to the weaker trochanteric region. Although the energy absorption pads is more flexible and may be more

comfortable to wear, research found that their force attenuation power is poorer than the energy shunting pads (Robinovitch et al. 1995). Kannus and co-workers also compared the force attenuation properties of different types of hip protectors. In their fall-simulating biomechanics study, they found that the energy absorption pads were only of marginal power to attenuate the impact force to a level right below the fracture threshold of the proximal femur in normal falling condition. However, for other falling condition with higher impact force such as falling with muscle in active contraction state, the energy absorption pads did not attenuate the impact force to a safety level. On the other hand, the energy shunting pads demonstrate its power to attenuate the impact force in most of the falling condition (Kannus et al. 1999). Okuizumi and co-workers applied silicon in their padding system and they found that by applying 12mm silicon pad alone, the impact force was significantly lower than that without the protection of the silicon pad. Similarly to Kannus' group, however, this energy absorption silicon padding did not attenuate the impact force to a level that was significantly below the fracture threshold of proximal femur, but with the addition of an energy shunting resin cover, the impact force was attenuated to a safety level (Okuizumi et al. 1998). Wiener's group also conducted the study on force attenuation properties of an energy shunting pads under real falling situation. They found that none of the volunteers sustained fracture after wearing the hip protector after falling down, and they also found that the hip protector can block up to 95% of the impact force to the trochanteric area (Wiener et al. 2002). In laboratory studies, it is found that energy shunting pads are superior to energy absorption pads in force attenuation. Most of the design of the energy shunting pads can attenuate the impact force to a safety level, and theoretically, when people wear these energy shunting types of hip protectors, most of the hip fractures can be prevented.

1.6.2 Clinical studies on prevention of hip fractures

Apart from laboratory study, there are a number of clinical studies showing the effectiveness of hip protector on prevention of hip fractures (Lauritzen et al. 1993, Ekman et al. 1997, Kannus et al. 2000, Chan et al. 2000, Harada et al. 2001, Woo et al. 2003, Forsén et al. 2004). Lauritzen and co-workers conducted the first large scale randomized controlled trial on nursing home residents and they found that hip protector could reduce up to 53% of risk of hip fracture and nine hip fractures were estimated to be avoided among the 247 subjects who wore hip protector during the study period (Lauritzen et al. 1993). Another large scale randomized controlled trial involving 1725 subjects done by Kannus and co-workers also demonstrated a reduction of 60% of hip fractures in the intervention group with the wearing of hip protector among nursing home residents, and they also found that only 41 persons need to use hip protector in order to prevent a single hip fracture (Kannus et al. 2000). Another study done in Northern Europe also showed significant reduction of risk of hip fractures to only 30% after wearing of hip protector when compared with the control group (Forsén et al. 2004b). Studies done in Asian countries including Japan and Hong Kong also demonstrated the effectiveness of hip protector in prevention of hip fractures. The study of Harada showed that the risk of hip fracture of people who wore hip protector was only one-eighth of that of the people who did not wear hip protector in a randomized controlled trial done in Japanese nursing home (Harada et al. 2001). Similar result was also found in a case control trial done in Hong Kong nursing home by showing the reduction of 82% risk of hip fracture after wearing of hip protectors (Woo et al. 2003). On the other hand, some studies failed to show the effectiveness of hip protectors on prevention of hip fracture (Cameron et al. 2001, Birks et al. 2003, Meyer et al. 2003, van Schoor et al. 2003a). The reason for that was

some of the study overestimated the hip fracture incidence and thus the sample size was planned too small to detect any significant difference (Cameron et al. 2001, Birks et al. 2003). While other study overestimated the force attenuation properties of the selected hip protector and the result turned out that a comparable hip fracture incidence was found in the intervention group to the control group (van Schoor et al. 2003a). Non-compliance to the hip protector was also one of the major causes of its ineffectiveness in some studies (Cameron et al. 2001, Meyer et al. 2003, van Schoor et al. 2003a). Cameron found that all the hip fractures found in the intervention group occurred when hip protectors were not being use, resulting in a potential of 50% of reduction of hip fracture risk was not detected (Cameron et al. 2001). Another study of Cameron done on community-dwelling elderly was also unable to show the effectiveness of hip protector in reducing hip fracture incidence as a result of poor compliance and lack of close monitoring as compared to those living in nursing homes (Cameron et al. 2003, O'Halloran et al. 2004). Nevertheless, it is found that when people wears hip protector, hip fracture seldom occurs, providing that the hip protectors are good enough for its force attenuation properties.

1.6.3 Cost-effectiveness study

Cost-effectiveness of hip protector has been researched extensively in the recent years. Some studies estimate the cost-effectiveness of hip protectors based on data from previous clinical trials (Segui-Gomez et al. 2002, Colón-Emeric C et al. 2003, Waldegger et al. 2003, Honkanen et al. 2005) while some based on own randomized controlled trials (van Schoor et al. 2004, Meyer et al. 2005). When compared with the cost of hip protectors and the associated cost of treatment of hip fractures that potentially hip protectors can prevent, the use of hip protectors are cost-saving

(Waldegger et al. 2003). Colón-Emeric reported that as far as the cost of hip protectors per person per 18 months not exceeding US$420, it is cost effective in prevention of hip fractures (Colón-Emeric et al. 2003b). Segui-Gomez further projected the analysis in the US and found that there would be an estimated net saving of US$1.2 billion per year, 6000 hip fracture related deaths and 32,000 quality adjusted life year gains if hip protectors were introduced in every 500,000 women who are 65 or older. (Segui-Gomez et al. 2002). However, the study of Segui-Gomez failed to prove hip protector was cost-effective for man except those who were 85 or older. The possible explanation for that was male had a generally lower hip fracture rates than female and lower compliance in the use of hip protector (Segui-Gomez et al. 2002). Another study even demonstrated that hip protectors were in advantage in terms of cost saving and improving quality of life when compared with other hip fractures prevention strategy including calcium and vitamin D supplements (Singh et al. 2004). However, cost-effectiveness analysis from two recent studies based on data from own clinical trials had different conclusion. The study of Meyer showed that application of hip protector was not cost saving unless the price of hip protector was lower (Meyer et al. 2005). The other study also came to the conclusion that hip protector was not cost-saving due to comparatively lower treatment cost of hip fracture in their own population and low effectiveness of hip protector as shown from own clinical trial (van Schoor et al. 2004). Oliver also warned that the previous estimations might overestimate the compliance and efficacy of hip protector, and hence the cost effectiveness of it in prevention of hip fractures (Oliver et al. 2006). Nevertheless, hip protector might be a cost-effectives measures if its cost could be lower and with better compliance. All the above cost-effectiveness studies were based on the previous clinical trials done in nursing homes, there are no study so far to

provide evidence on the cost effectiveness of hip protector on community-dwelling elderly.

1.7 Problems on the use of hip protectors

Although there are a number of studies proven the force attenuation properties, clinical efficacy in prevention of hip fractures as well as cost-effectiveness of hip protectors, there are some major problems found in the use of hip protectors, which affects its effectiveness in clinical practice.

1.7.1 Discomfort

Among the problems associated to the use of hip protectors, discomfort is the major one. A study found that nearly 40% of elderly stopped wearing hip protectors because of discomfort (Villar et al. 1998). It is also not uncommon to see discomfort in the use of hip protector as reported in other studies (Birks et al. 1999, Hubacher and Wettstein 2001, Cryer et al. 2002, Patel et al. 2003). The problem of discomfort is usually more serious during night time (Parkkari et al. 1998, van Schoor et al. 2002). Probably, the design of the hip protector account for the problems of discomfort. It is observed that most of these studies used energy-shunting type hip protectors, which are usually made of hard plastics (Parkkari et al. 1998, Villar et al. 1998, Birks et al. 1999, Cameron et al. 2001, Hubacher and Wettstein 2001, Cryer et al. 2002, Patel et al. 2003). The hard plastic pads hinder the users to perform turning from supine to side lying or vice versa during sleep and makes the users feel uncomfortable as a result of the pressing that the pads given. Therefore it is not unexpected to see the problem on use of hip protector is more serious at night time, especially for thin person (Cameron et al. 2001). Hubacher and co-workers even found a portion of subjects in their study

stop wearing hip protector because of pain or tender spots caused by wearing hip protectors (Hubacher and Wettstein 2001). For studies using energy absorption pads, problems on discomfort are not that serious when compare with that of the energy-shunting type hard shields (Chan et al. 2000), since the materials for making these types of pads are usually made of softer materials like foams and plastozote (a foam like cushioning materials), and there is not as much as the pressing that an energy-shunting pad may give. However, in order to make the pads more effective in force attenuation, the energy absorption pads are usually thicker and larger than the energy shunting type, it is more clumsy and bulky when wearing, which is another big problem in hindering the use of hip protector.

Apart from the pressing feeling that the pads provided, fitting is also another associated factor for discomfort. Tightness is a common problem of hip protectors, which in turn make the users feel uncomfortable. Butler and co-workers found that the discomfort associated with tightness was one of the major concerns for subjects to wear hip protector (Butler 1998). Similarly, in the study of Villar, a quarter of the subjects stopped wearing hip protector because of poor fitting (Villar et al. 1998). Hubacher found that experiencing hip protector as comfortable or fit was a significant discriminator between the hip protector wearers and drop outs (Hubacher and Wettstein 2001).

1.7.2 Extra effort in wearing

Apart from discomfort in wearing hip protector, extra effort is need for most of the user to wear and remove hip protector when compare with that of wearing underwear. Hip protectors are usually designed of certain degree of tightness, which is

necessary for holding the pads in position and keep the pads in contact with the skin. However, besides the problems of associated discomfort, this tightness often results in extra effort in putting on or removing the pants. Although there was no study done so far to quantify this problem, it was not uncommon to see this problem from the feedback of the hip protector users, and some of them discontinued to wear hip protector because of experiencing difficulties or spending extra time in wearing or removing hip protectors, especially among people with physical difficulties (Lauritzen et al. 1993, Villar et al. 1998, Birks et al. 1999, Patel et al. 2003, van Schoor et al. 2003b). A recent study also showed that higher level of physical disabilities was a significant barrier to the use of hip protector (Warnke et al. 2004). Patel also found that a number of people with high risk of fracture did not wear hip protector simply because they could not wear them independently (Patel et al. 2003). On the other hand, people with adequate assistance in wearing and removing hip protector are more compliant to hip protector (van Schoor et al. 2003b). The extra effort in wearing hip protectors can also affect some normal activities of daily living like toileting. Some users who are independent in toileting will need assistance from nursing home staff to do so after wearing of hip protectors (O'Halloran et al. 2005) while a number of users report extra time is needed for removing the hip protectors for toileting (Suzuki et al. 1999, Yasamura et al. 1999). This may, on the other hand, increase the risk of fall. Actually, a case report showed that a person with Parkinson's disease fell when trying to remove the undergarment underneath the hip protector in toilet (Specht-Leible et al. 1999).

1.7.3 Appearance after wearing

The appearance after wearing hip protector also account for another major

problem to the acceptance of hip protector. In an explorative study on acceptance of hip protector, one of the major concerns was the appearance of the hip protectors, especially for female users (Butler et al. 1998). More than half of the subjects concerned about whether the hip protector would be shown while wearing the hip protector (Myers et al. 1995). Unattractive appearance of the hip protector and being not fashionable are the barriers for the acceptance of hip protector. A quarter of the subjects refused to try hip protector in a study because they did not like the appearance of themselves after wearing hip protectors (Patel et al. 2003). A recent study even reported the comment of the hip protector as distaste by some of the subjects who did not accept the wearing of hip protector (Forsén et al. 2004a). Thus these negative perceptions towards hip protector have become a significant barrier to the use of hip protector by a considerable portion of potential users.

1.7.4 Urinary incontinence

It is not difficult to associate the problem of people with urinary incontinence in the use of hip protectors. People with urinary incontinence will experience extra effort for frequent wearing and removing the tight pants as a result of frequent toileting and need more pants for exchange when the pants are contaminated by the leaked urine. Therefore, urinary incontinence was reported as a barrier to the use of hip protector (Butler et al. 1998, Birks et al. 1999, van Schoor et al. 2002). Although a recent study found that people with urinary incontinence might have higher compliance towards hip protectors due to they were more get used to the tight pants as they were used to wear diapers (van Schoor et al. 2003b), the problems of fitting the diapers or the incontinence pads underneath the hip protectors need to be solved for the use of hip protector among this group of people.

1.7.5 Other problems

Apart from the major problems described above, some other problems regarding to the use of hip protectors were also reported in literature. These problems included heat rash (Villar et al. 1998, Forsén et al. 2004), forgetfulness (Villar et al. 1998), perceived lack of personal risk (Chan 2000, Patel 2003), lack of knowledge about hip protectors (Stokes 2005), problems related to laundering (Butler et al. 1998) and financial concerns (Cryer et al. 2002, Stokes et al. 2005). These factors bring additional challenge to the use of hip protectors and its effectiveness.

1.8 Acceptance and Compliance of hip protectors

Poor acceptance and compliance of hip protectors as a result of the problems that encountered in the use of hip protectors and the poor perception in the use of hip protector that described above are the major obstacles for hip protector to be an effective measure to prevent hip fractures.

1.8.1 Acceptance

Acceptance by the users is important for the prescribed intervention to be successful. However, from literature review, acceptance of hip protectors was poor. The definition of acceptance has been suggested to be the percentage of subjects agree to wear hip protector and should be calculated by dividing all subjects who agree to wear the hip protector by the total number of subjects who were asked to wear hip protector (van Schoor et al. 2002). Based on this definition, the variation of the hip protector acceptance of previous studies range from 37.2% to 69%, with mean acceptance of 52.9% and median acceptance of 53% (Table 1.1). The acceptance of hip protector was better among the nursing home residents, with an average of 55% of

acceptance, compared to 38% of acceptance among community-dwelling people (Patel et al. 2003).

1.8.2 Compliance

Compliance to hip protectors has been reported to be the chief problem in almost every study in investigation on the use of hip protectors. It is not unexpected to see that there was low compliance of hip protector in literature as a result of the problems that encountered in the use of hip protector that have been described above (van Schoor et al. 2002, Parker et al. 2005, Sawka et al. 2005). Although different definition of compliance were used by different studies, Kurrle and co-workers proposed to have the standardized definition of compliance as the wearing of hip protectors in accordance with the recommendations of the study protocol and can be measured in the following ways: (1) the amount of time the hip protector is worn or (2) percentage of fall where hip protector was being worn (Kurlle et al. 2004). Studies with follow up time more than six months were reviewed and compliance was calculated according to the above definition. It was found that the average wearing time of hip protectors by the subjects were only 44.4% (day time, range from 22% to 70%) and 30.6% (night time, range from 3% to 70%) across a mean study period of 11 months. There were 54.7% of fall occurred when hip protectors were being worn. The compliance of hip protector among community dwelling elderly, which was basically relied on the self-report of the subjects (45.5%), were slightly higher than those living in nursing homes (43.8%), which were mostly recorded by nursing staff or research staff. There was about a half of the subjects discontinued to wear hip protector within the study period of previous studies (Table 1.1 – 1.2). No matter what measurement methods are used in measuring compliance, it is noted that compliance

is poor for both community-dwelling elderly and nursing home residents in all times of the day. In fact, there were more and more recent studies found that the problems of compliance might also affect the effectiveness of hip protector (van Schoor et al. 2003a, Birks et al. 2004, O'Halloren et al. 2004, Sawka et al. 2004).

1.9 Strategies to improve compliance of hip protector

In order to improve effectiveness of hip protectors, it is necessary to improve the compliance of it. Hubacher and co-workers proposed three areas of factors associated with the compliance of hip protectors: (1) the design of hip protector, (2) the social-demographic, physical and psychological characteristics of the target group and (3) the attitudes of the nursing staff (Hubacher and Wettstein 2001). Therefore, different strategies on improving compliance with respect to the hip protector, the users and also the carer/nursing staff are important.

1.9.1 Better design of hip protector

The design of hip protector is probably the most important factors that contribute to the compliance of hip protectors. Based on previous reported problems of current hip protectors, better designs which are more comfortable and convenient to wear and not affecting the appearance as much as possible after wearing seems to be more acceptable by the users. It is hypothesized that different hip protectors may have different compliance. The energy shunting type hip protectors were used predominantly in most of the previous studies, only a few use the energy absorption pads (Table 1.1-1.2). There were some studies compared the compliance between the energy shunting and energy absorption hip protectors (Suzuki et al. 1999, Yoshimura et al. 1999, O'Halloren et al. 2005). Although there were limitations in the design of

both types of hip protectors, it is found that the compliance of energy absorption type hip protector was slightly higher than the other as they are more comfortable to wear. However, these studies are mainly explorative in nature and of small sample size, further investigation is necessary on designing a better hip protector in order to achieve better compliance.

1.9.2 Encouragement/support to the user

Attitude of the people towards the use of hip protectors and the practical problems when wearing hip protectors are also crucial concerns in the compliance of hip protectors. Studies found that education sessions and fall risk counseling might have beneficial effect in the use of hip protectors (Meyer et al. 2003, Fan et al. 2005). The education session may help users to conceptualize the risk and consequences of hip fractures and how hip protectors may help them to prevent hip fractures. It is even more important for improving the initial acceptance of hip protectors. On the other hand, unsolved practical problems associated with the use of hip protector can also be the barriers for continue use. Kurlle and co-workers found that people with low self efficacy for wearing hip protectors, one or more perceived barriers to wear hip protectors and poor self-rated health are predictors of low compliance (Kurlle et al. 2004a). Thus management of the difficulties in wearing hip protectors and the medical problems that may associate with the use of hip protectors are essential to facilitate the use of the hip protectors (Cryer et al. 2002). Examples of practical help may include assistance in wearing hip protectors for people who find difficulties in wearing by themselves or providing more pairs of hip protectors for exchange in consideration of laundry problems or frequent contamination by people with urinary incontinence, which have been proven to be determinants of compliance (van Schoor

et al. 2003b).

1.9.3 Support from nursing staff/carer

Support of the nursing staff and also the carer are also crucial in the facilitation of the use of hip protectors. It is found that nursing staff with positive attitude towards the use of hip protectors and with the commitment to the implementation may have positive effect on compliance of hip protector among nursing home residents (Parkkari et al. 1998, Cameron et al. 2001, Cryer et al. 2002, Forsén et al. 2004a). It is also found that the attitude of the staff may influence on that of the residents, and compliance of hip protectors were higher in nursing homes that staff were with positive attitude than those where the staff were not (O'Halloran et al. 2004). Formal records in the residents' daily log book is also important for the communication between nursing home staff which facilitate the monitoring of the use of hip protectors and the handling of the problems of hip protector (Burl et al. 2003). Therefore, besides the education of the users, education of the staff is also important. Research found that programs which facilitate the increasing concern about frequent fallers and the usefulness of hip protector by the nursing home staff could be beneficial in achieving high compliance in the use of hip protectors (Harada et al. 2001). It is also important for facilitation of staff in choosing and focusing on the highest risk groups to wear hip protectors so that higher portion of falls occurred would be protected by the hip protectors (Forsén et al. 2004b). For community dwelling people, support of the research staff or community nursing staff in the form of regular telephone follow up or visitation to remind and encourage the wearing of hip protector may be beneficial to the compliance of hip protectors (Cameron et al. 2003), though further investigation is needed to justify.

1.10 Rationale and objectives of present study

The seriousness of the problems of hip fractures will increase dramatically in Hong Kong and China in the foreseeable future due to rapid population aging, which will bring great challenge to both the welfare and medical systems of the society. Although more investigations are needed to accumulate evidence, hip protector has been shown by a wide variety of studies to be one of the most effective strategies in prevention of hip fractures, as far as it has sound force attenuation properties and high compliance. However, base on current evidence, there are still some limitations towards the use of hip protector among local Chinese elderly.

Firstly, there is no commercially available hip protector which is designed for Chinese people, most of the designs that are available are designed in countries with dominantly Caucasians. However, since the body figure of Chinese people will be differed from that of the Caucasians, directly apply those hip protectors to Chinese people will be a problem of fitting.

Secondly, there was no previous study done on investigating the compliance of hip protector among Chinese elderly, which is a crucial factor for the effectiveness of hip protector. There was only one study done in Hong Kong on the efficacy of hip protector so far (Woo et al. 2003), however, due to short follow period of only one month, limited information is known about the compliance.

Finally, there are only little is known about the determinants of compliance and non-compliance of hip protector among Chinese elderly, which would facilitate hip protector wearing in clinical practice. The social demographics, culture, physical

environment in Hong Kong are very different from that of the Caucasian countries, the profile for determinants of compliance among Chinese elderly may also be different from that of the Caucasians.

Therefore, the objectives of this study are to (1) develop a hip protector which is of sound force attenuation properties and suitable to be worn by Chinese elderly; (2) evaluate the acceptance and compliance rate of the hip protector among the Chinese elderly; and (3) investigate the determinants of compliance and non-compliance of hip protector among Chinese elderly

Figure 1.1 X-ray of a typical hip fracture (fracture neck of femur)

Table 1.1 Hip protector studies done in nursing home settings

Study	Type of HP	Sample Size	Compliance definition	Rating method	Compliance rate
Lauritzen et al. 1993	Polypropylene HP	N=247	None provided	None provided	24% of fall was protected
Heikinheimo et al. 1996	Safety pants	N=36	% of subjects still wearing hip protectors at the end of study	None provided	68% of user still wearing HP at the end of 12 months 77% of falls protected
Ekman et al. 1997	JOFA AB	N=302	Not specified	None provided	44% wearing hip protector 27% of falls protected
Parkkari et al. 1998	KPH	N=19	% of wearing time during walking hours	Research diary by caregivers	Acceptance 63% Mean time used in 3 months: 91%
Becker et al. 2000	Not specified	N=346	Not specified	Measured from getting up in morning till bedtime Measured monthly	Acceptance 37% Compliance: fully adherent 67% (mean, nine months)
Chan et al. 2000	HipSaver	N=40	% fall protected		50% fall protected

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Table 1.1 Hip protector studies done in nursing homes settings (con't)

Study	Type of HP	Sample Size	Compliance definition	Rating method	Compliance rate
Kannus et al. 2000	KPH	N=650	% of days wearing % of falls in protection	Daily checked by caregivers	Acceptance 69% Compliance 48% Protected fall: 74%
Cameron et al. 2001	Safehip 4 pairs	N=86 Repeated fallers/fall requiring admission	Not specified	Checked by adherence nurse at scheduled visit	Mean (12 months): 57% (day time); % of protected fall: 54% day; 36% night
Harada et al. 2001	Local shell-shaped	N=88 (Female) (assigned wearers)	% of complete wear and incomplete wear	Daily checked by care staff	Complete (12 months): 70% Incomplete 17%
Hubacher et al. 2001	HIPS	N=262	% of wear hour of the checking days	Checked in 20 days spread through 10 month	Initial acceptance 68.2% 47% of wearer discontinued in 10 months mean compliance: 49% drop outs: 9.8%
Cryer et al. 2002	Safehip	N=299	% of sessions the hip protector were wearing	Daily (divided into 4 sessions) by specific care staff	Acceptance 51% Mean (6 months): 37% (day) and 3% (night)

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Table 1.1 Hip protector studies done in nursing homes settings (con't)

Study	Type of HP	Sample Size	Compliance definition	Rating method	Compliance rate
van Schoor et al. 2003	Safehip	N=276	% of people wearing HP at each visit	Unannounced visit at 1, 6, 12 month	1, 6, 12: day (night) 60.8%(14.8%), 44.7%(16.1%), 37%(8.8%)
Woo et al. 2003	Local make HP	N=302	% of hrs hp were wearing	Daily checked by staff	65% one month
Forsen et al. 2003 Forsen et al. 2004a Forsen et al. 2004b	Safehip	N=1040	% of acceptance % of continued use % of use at given points of time % of use at fall	Registered by project employees daily	Acceptance 55% 28% stopped within 12 months 43% continue after 12 months Day time: 35% (1st month), 22% (12th month) Night time: 40% (1st month), 36% (12th month) Protected fall: 70%
Meyer et al. 2003, Warnke et al. 2004	Safehip 3 pairs	N=459	% of protected fall	Recorded by nursing staff	68% of fall protected
O'Hallonran et al. 2004	Safehip	N=1366	% residents wearing HP at checking time	Checked by employed staff at scheduled time	Acceptance 37.2% Drop from 33.4% at 4 weeks to 19.9% at 72 weeks

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Table 1.1 Hip protector studies done in nursing homes settings (con't)

Study	Type of HP	Sample Size	Compliance definition	Rating method	Compliance rate
O'Hallor an et al. 2005	Safehip HipSave r	N=109	Percentage day time use	Unannoun ced visit	Initial acceptance 42% 12 weeks – 43% still wear HP, mean rate 48.6% (Safehip 51.4%, HipSaver 48.6%)

Table 1.2 Hip protector studies done in community

Study	Type of HP	Sample size	Compliance definition	Rating method	Compliance rate
Villar 1998	Polypropylene with plastozote lining (x3)	N=101 female	Not specified	Random visits each fortnight	27% complete 12 weeks trial 54% dropped out within 1 week
Thompson 2000	Safehip	N=61 3-months	Wearing each day	Not specified	Acceptance 70% 46% wore HP most of the days
Birks 2003	Safehip (x3)	N=182	Not specified	Self-report	34% at 14 months
Patel 2003	Safehip (x3)	N=32	Not specified	Self-rated daily cards on number of hours wearing HP	Initial acceptance 38% 50% of subject still using HP at 12 months with mean compliance 60% at day time
Cameron 2003 Kurrle 2004	Semirigid hip protector	N=302 Female	Wearing hip protector at least half of day	Self report	57% to 42%, 12 to 24 months 51% protected fall
Birks 2004	Safehip (x3)	N=1388 female	Not specified	Self-report	31% at 12 months reported wearing most of the times 41% protected fall at 12 months

Methodology

II. METHODOLOGY

There were three phrases in the current study. In the first phase, a modified hip protector specially designed for the suitable use among Chinese elderly was developed. The hip protector developed was then undergone mechanical testing to evaluate its force attenuation properties in the second phase. Finally, the tested hip protectors were distributed to the elderly for the compliance study. The details of the methodology are described below.

2.1 Development of hip protector

Better designs of hip protector may achieve better acceptance and compliance in the use of hip protectors (Hubacher 2001). There were several modifications made in the present design of hip protector, including both the pants and pads.

2.1.1 Design of the pads

There were several modifications made to the current design of the pads. Firstly, most of the current hip protectors were either energy shunting type or energy absorption type (O'Halloran 2005b). However, in the present design, rather than a purely energy shunting pads or a energy absorption pads, a combination of the energy shunting and the energy absorption types was used. The skeleton of the present design was similar to that of the other energy shunting types, but in addition to that, a layer of a soft energy absorption material is added to the inner side of the pads to make the user more comfortable while wearing (Figure 2.1).

Secondly, Orfit (ORFIT Industries, New York, United States) was used as the

material for making the pads in the present design. Orfit is a type of semi-flexible plastic with good recovery ability after compression and is an allergy-free plastic for direct application to skin (Edsander-Nord A, 1996). It is safe to be applied with direct skin contact and therefore it is also safe for making the pads for hip protector to avoid most of the allergic response to plastic though the pads are not directly in contact with the skin. A 3.2mm thickness Orfit is used for making the pads as this thickness is standardized for making brace and splints and is readily obtainable from supplier.

In addition to the hard plastic, a layer of the silicon was added to the inner side of the hard plastic (Figure 2.1) under the consultation of the Jockey Club Rehabilitation Engineering Centre of the Hong Kong Polytechnic University. The same thickness (12mm) of silicon layer as the model developed by Okuizumi was used to develop our first prototype (Okuizumi 1998). However, this prototype weighted 140g, which may be too heavy for practical use. Further two prototypes with 7mm and 2mm thickness silicon padding were made. The 2mm thickness was chosen because it was the thinnest one that the manufacturer could make. The 7mm protocol was the middle in thickness between the 2mm and 12mm prototypes. In order to further reduce the weight of the pads, silicon was only applied to the edge of the hard plastic shield, with the middle part being hollow. The weights of the three prototypes were then 110g (12mm), 75g (7mm) and 40g (2mm).

Thirdly, the hard plastic and the silicon pads were sewed into a bag made of water-proof cloth (Figure 2.2). This cloth bag serves many purposes. First, users are more convenient to handle the pads for inserting to and removing from the pockets of the specially designed pants (described below in session 2.1.2) for laundry. Second,

the water-proof cloth can guard sweats that may contaminate the pads. And finally, it is more cosmetically attractive. Instruction on proper positioning of the pads into the pants is also printed on the convex side of the pads.

Finally, the anthropometric data of local elderly was measured for deciding appropriate size of the pads (described below in session 2.1.2.2). For the hip protectors to be effective in prevention of hip fractures, the pads should be positioned precisely with the convex region place right beyond the greater trochanter. Since this hip protector was not tailored for each user, the investigator collected anthropometric data of local elderly for deciding the optimum pad size for sufficient coverage of the greater trochanter after accounting for individual variations in body figure.

2.1.2 Design of the pants

Since there were no commercially available hip protectors made for local users, and most of other products are made for Caucasians, direct application of those products may not fit the local users well due to anthropometric difference (Ross 1996). Thus, besides the pads, pants specially designed for local users are necessary. The pants were designed in collaboration of the Institution of Textile and Clothing the Hong Kong Polytechnic University. There are three areas of consideration in making the pants: the fabric materials, sizes of pants and the pattern design of the pants.

2.1.2.1 Fabric materials

The selection of fabric materials for the pants should base on the function of the pants and the physical environment where the pants to be wore. There are a number of characteristics of the fabric materials considered as important for making the pants for

hip protector. Since the major purpose of the pants is to help holding the pads in position, the pants should not be too loose, otherwise it may not be able to keep the pads in right position while wearing. The pants should, on the other hand, be slightly tightly fit so that it provides necessary pressure to keep the pads in place. Therefore, the fabrics should be elastic and with good recovery ability after stretching. Secondary, the fabric materials need to be durable and resistive to shrinkage after laundry (Cameron 1994). This is also important for the pants to maintain its function on holding the pads in right position after repeated use, particularly for users with urinary incontinence who require frequent change of the pants. Thirdly, since the pants are supposed to be worn as underwear, the fabric should be skin-friendly and therefore a high percentage of natural fabric which is soft and comfort is needed as the major composition for the pants. It should also be with good air permeability since satisfactory ventilation of the fabrics could also improve comfort. Finally, since the pants are designed for elderly in Hong Kong, in which the weather is hot and humid on the majority of days in a year. Therefore the fabric materials should have good moisture absorbance capacity so that it can absorb the excess sweating of the user and avoid the sticky feeling after wearing especially in summer time.

Based on the above requirements, consultation on possible suitable fabric materials was made to the Institute of Textile and Clothing of the Hong Kong Polytechnic University. Knitted fabrics were recommended for making the pants as they are generally more elastic. Four types of knitted fabrics which possibly matched the requirements were selected. The detailed composition of the fabrics was summarized in Table 2.1. All the selected fabrics are of high composition of cotton fiber, which is a natural, soft and skin-friendly fiber. Different portions of synthetic

fibers are added into the cotton to make the fabric material more durable and assistive to shrinkage. In order to compare the suitability of the four selected fabrics, a series of standardized fabric functional tests were done on each fabric according to the requirements stated above. The tests include (1) Air permeability test, (2) Moisture absorbency test, and (3) Dimensional stability after laundry. All the functional tests were done within the fabric laboratory of the Institute of Textile and Clothing by a well-trained technician with standardized equipment and procedures.

The Air permeability test was done under the standardized procedure stated in "ASTM D 737 – 96 Standard Test Method for Air Permeability of Textile Fabrics" (ASTM International 2005). The testing apparatus consist of: (1) A test head that provides a circular test area of 5.08cm^2; (2) A clamping system to secure test specimens of different thickness under a force of at least 50±5 N to the test head without distortion and minimal edge leakage underneath the test specimen; (3) A mean for drawing a steady flow of air perpendicular through the test area and for adjusting the airflow rate; (4) A Pressure Gage or Manometer connected to the test head underneath the test specimen to measure the pressure drop across the test specimen in Pascal of water with an accuracy of ±2%; and (5) A Flowmeter to measure air velocity through the test area in cc/s/cm^2 with an accuracy of ±2%.

Five samples of each fabric were collected for the test. Each test specimens was placed onto the test head of the test instruments with the right side of the fabrics faced upward (towards high pressure side). It simulated that the air flowed from the external environment towards the user who wearing the pants. The instrument was operated to create pressure difference between the upper side and the lower side of the fabric.

Tune slowly until pressure difference of 100Pa was created. The air flow velocity was recorded from the readings displayed on the Flowmeter. The rate of air flow is measured in cc/second.

"AATCC Test Method 79-2000 Absorbency of Bleached Textiles" was used for determining the ability of the fabric in moisture absorbency (American Association of Textile Chemists and Colorists 2005a). The instrument of the test included an embroidery hoop, a burette with stand and a stop watch. During the test, the embroidery hoop was used to keep each of the fabric specimens in a taut surface. A standardized volume of water droplet was dropped from a fixed height at 10mm to each specimen with a burette. For each specimen, 5 droplets of water were delivered randomly to 5 different portions. The time required for the water droplet to disappear was recorded.

"AATCC Test Method 135-2001 Dimensional Changes in Automatic Home Laundering of Woven and Knit Fabrics" was used for the test on dimensional change after laundry (American Association of Textile Chemists and Colorists 2005b). The instruments of the test include an automatic washing machine and tumble dryer (Kenmore Heavy duty 70 Series, California, USA), 1993 AATCC Standard Reference Detergent, hemmed pieces of bleached cotton sheet, indelible ink marking pen and measuring tape. Five 380mm* 380mm specimens for each fabric were collected. Three 250mm (10 inches) pairs of bench marks parallel to the length of the fabric and three 250mm pairs of bench marks parallel to the width of the fabric was marked on the specimens. All the marked specimens were undergone the laundry process. The washing temperature was kept at 27°C. Since the washing load of the machine was

fixed to 1800g, 960g of the hemmed cotton sheet was added to the specimens for washing at the same time. According to the test manual, 66g of the 1993 AATCC Standard Reference Detergent was added for washing. The water level was adjusted to "medium" (around 18 ± 1 gal) while the washing cycle was turned to "normal, knit, 8 minutes". The washing process lasted for about 30 minutes. After that, the specimens were taken to the tumble dry machine for undergoing 30 minutes tumble drying process. The whole cycle of the laundry process were repeated for 5 times for the same specimens with 24 hour gap between each cycle. The distance between each pair of bench marks were measured after the fifth laundry cycle.

2.1.2.2 Anthropometric measurement

Pants that are well-fit to the users will increase comfort and are important for improving compliance. Before the design of the pants, anthropometric measurements were done. The hip protectors were designed to be worn by elderly women (rationale described below in session 2.3.2). Since there was no relevant anthropometric data available for Chinese old ladies, female volunteer with age 70 or older from an old age home were recruited for anthropometric measurement. A sample size of 70 was required based on a previous local study on anthropometric measurement of young ladies (Yu et al. 1999). The measurements included the circumference of waist, hip and thigh (first round), vertical distance of the three circumference measurements, and the location of the greater trochanter to the waist level. The measurements were illustrated in Figure 2.3. All the measurements were done by a well-trained female research staff with tape measure. The precision error of the measurement was ± 0.5mm.

2.1.2.3 Pattern design

There were two modifications on the design of the pattern of our model. First, a crotch piece (Figure 2.4) was added on the present design. Usually the crotch of the pants is where the seams meet together, such as that of a boxer, which makes the user feel uncomfortable, especially for female. Therefore, a crotch piece is usually added for female underwear to avoid the seams meet directly at the crotch. The present design adopts the pattern of female underwear by adding a crotch piece to make the users feel more comfortable. It is also useful for holding the incontinence pads for users who suffer from urinary incontinence. Second, a woven piece was added to the lateral sides of the pants, vertically from waist to thigh opening, in which the pockets for holding the pads are sewed. Since the woven is a rather non elastic fabric with better dimensional strength than that of those elastic fabrics, it is useful for holding the pads in place against gravity.

2.1.3 Trial use of hip protector

Six female elderly hostel residents with age over 70 were recruited to wear the three prototypes. They were required to wear the three hip protectors overnight one by one with random order. Feedbacks on wearing the prototypes were collected by the investigator.

2.1.4 Calculation and statistical method

Descriptive statistics including means and standard deviations was used to summarize the anthropometric data of the volunteers. Size charts of the pants were developed by obtaining means of the measurement of different size groups (Yu et al. 1999). In this study, the data on measurement of the waist circumference was used to

determine different size groups. A histogram on the measures of the waist circumference was plotted with Y-axis being the circumference and X-axis being the number of people. The X-axis was divided into 5 equal blocks and the mean of the measurements of the subjects on that particular block was used to make the particular size. Five sizes (extra small, small, medium, large and extra large) of the pants were developed according to the mean data in the five blocks.

For the comparison on the properties of different fabric materials, means and standard deviation were calculated, one-way analysis of variance (one-way ANOVA) with post-hoc comparison were used to compare the mean difference among different samples. Significant level was set at $p<0.05$. All the statistic tests were performed using the software Statistical Package for Social Science (SPSS) version 13.0 (SPSS Inc, Chicago, IL, USA).

2.2 Mechanical test on force attenuation properties

The prototypes of the pads were undergone mechanical test on force attenuation properties before the application on human subjects.

2.2.1 Testing system

A drop-weight test was set up as the testing system (Figure 2.5 – 2.6). It consist of a force platform (Kistler 9285, Kistler Instrument Corp, NY, USA) with four identical force sensors which can record the total force that acts onto the platform (Figure 2.7), a 7kg lead shot (which is commonly used by athletes) to provide the direct impact to the force platform. The sampling rate of the force platform was set to be at 2000Hz so that it had adequate sensitivity to record the change of impact force

within the short impact time, which is estimated in millisecond (Weiner et al. 2002). A lead shot was used because a sphere would provide the same impact even though the orientation of the lead shot was different at the moment of being released. This was important to ensure the test-retest reliability and minimize the systemic error of the test. The lead shot was hold to a metal frame right above the force platform by a fish line, which was adjusted so that the lead shot was at the desired height above the force platform. The fish line was cut to let the lead shot drop freely on to the platform to provide the impact. A plastic tube with diameter 20cm is mounted to the force platform to make sure the lead shot was kept inside the tube after each impact so as to avoid the damage of other parts of the force platform by the lead shot.

2.2.2 Simulation of impact force and identification of dropping height

Before the impact experiment to the hip protector, the amount of impact force acting on the hip which simulate typical falls situation needs to be determined. According to an *in vivo* study on fall biomechanics, for a lateral fall landing on hip with muscle in relax state (low impact), the impact force was around 5600 N (Robinovitch et al. 1991). On the other hand, the impact force could be as high as 8000 N with muscle in contraction (high impact) (Robinovitch et al. 1991). To be more conservative, forces which were higher to the above values in both the low and high impact were created. With reference to the impact experiment done by Kannus and co-workers (Kannus et al. 1999), the impact force used were somewhat around 7000 N and 10000 N for the low impact and high impact condition respectively.

According to Newton's Second Law and the Law of conservation of energy, the following equation was generated for estimation of the impact force and dropping

height:

$$F*t=m*(2*g*h)^{1/2}$$

F: impact force (N)

t: impact time (s)

m: mass of the lead shot (kg)

g: acceleration of gravity, which is equal to $9.8ms^{-2}$

h: dropping height (m)

According to the above formula, however, the dropping height which is necessary to generate the desired amount of force can not be calculated directly since the impact time is also an unknown. In order to identify the dropping height for each impact condition, the lead shot was released from 5 cm above the platform, and with 5cm increment each time until the desired amount of impact force were generated. Figure 2.8 summarized the amount of impact force against different dropping heights. The results showed that the 7kg lead shot would provide around 10000N of impact force when it was dropped at about 25cm above the platform and 7300N of impact force when the dropping height was 15cm. The impact time of both the impact condition was about 1.5 ms. These amount of forces were also recommended in other study (Kannus et al. 1999).

2.2.3 Testing method

After the dropping heights were determined, five drops for each impact conditions were performed to make sure the readings are reproducible. The dropping height was measured by the ruler with precision error of ±0.5mm. Ten identical

samples for each prototype were provided by the manufacturer (Hong Kong Wah Tung Ltd., Hong Kong, China) for the test. The plastic shield was manufactured by a specially designed plastic mould to make sure each sample is identical. The thickness of the silicon pads varies by ±0.5mm across different samples of the same prototype. Five samples for each prototype were used for the impact experiment under the low impact condition. Five repetitive impacts were made to each sample. The process was repeated for the other five new samples of each prototype under the high impact condition. The peak amount of force recorded by the force platform in each impact experiment was the primary outcome. The duration of each impact was also recorded.

2.2.4 Calculation and statistical method

Descriptive statistics including means and standard deviations were calculated for all the measurements including impact force and impact time. ANOVA test was used to determine the significance of differences between means of different prototype in both the impact time and impact force. ANOVA test was also used to measure difference in the impact force of the successive impacts to the same sample. Significant level was set to be at $p<0.05$. SPSS version 13.0 (SPSS Inc, Chicago, IL, USA) was used for all the calculation.

2.3 Compliance study

2.3.1 Setting

The present compliance study on hip protector wearing was conducted in elderly hostels. The reasons for choosing elderly hostels (EH) are: first, it is easier for monitoring the compliance of elderly on wearing hip protector by the staff in the

hostels and second, the fall incidence in elderly hostels are higher than that among community-dwellers (Chan et al. 2004, Chu et al. 2005), the elderly hostels residents may be at more benefit to wear hip protector. According to the standard categorization by the Social Welfare Department of Hong Kong, EH were those providing residential service, meal service and limited day care service for elderly who are 65 or older who cannot live independently in community. (Eligibility of elderly hostel, Social Welfare Department, 2005). Since the sample size of the study was only around 180 (described below in session 2.3.7), it was estimated we could recruited enough subjects from 4 to 5 hostels. Five EH were randomly selected from the list of elderly hostel that list in the Social Welfare Department of Hong Kong. Invitation letters were sent to these selected hostels to invite them to participate in the study.

2.3.2 Subjects

Female residents from the EH were recruited to participate in this study, since female are at higher risk of hip fracture than male (Lau et al. 1999, Colon-Emeric et al. 2003a). The inclusion criteria for this study were (1) female residents with age 70 or above; (2) with mobility better than wheelchair bounded; and (3) able to stand independently without any aids. We believe the subjects with the above characteristics might be the potentially suitable users in the future and make the results of this study more applicable in practical situation. Since people at older age were at higher risk of hip fracture (Lam et al. 2005, Mayphew et al. 2005), early use of hip protector should be encouraged before they get too many physical difficulties in wearing hip protector at an older age, which might hinder the use of hip protector. People at the age of 70 may be a suitable start since their risk of hip fracture should be at certain high level but not yet got many difficulties in wearing hip protector. (Kannus et al. 2000).

Actually some of the large trials in old age homes also recruited residents with age 70 or older in their studies (Lauritzen et al. 1993, Kannus et al. 2000, van Schoor et al. 2003a). People with mobility better than wheelchair bounded are the ones with risk of hip fracture which may be the result of fall incidence during locomotion. On the other hand, hip fracture seldom happened in people who are wheelchair bounded unless there is accident during transfer. Safety in wearing hip protector is also a crucial issue. A person with adequate standing ability is important for pulling up the pants safely while wearing hip protector. Thus people who cannot stand independently without aids were excluded from this study due to safety concern.

All the residents in the elderly hostels meet the above criteria were invited to participate in this study.

2.3.3 Study design

This is a 12-month prospective study to follow up eligible subjects on the compliance of modified hip protector.

2.3.4 Implementation procedure and intervening Program

2.3.4.1 Liaison with the heads and responsible staff in the elderly hostels

Before the implementation of this study, a meeting with the heads and responsible staff from the four elderly hostels was arranged. During the meeting, the purposal of the study was explained. A literature review on the effectiveness of the hip protector in old age home residents was introduced to them. Samples of the modified design of hip protector were shown and the strength of this design on the fitting of

local elderly was also explained. A research protocol (Appendix 1) summarizing the implementation procedure was left for the participating elderly hostels for reference. The heads of each elderly hostel identified contact persons for monitoring the study at their hostels. The contact persons were also responsible for selecting the appropriate subjects for this study.

2.3.4.2 Education program for hostel staff

Four identical two-hour education programs were arranged to all the staff of the four participating hostels. The program included introduction on the epidemiology of hip fractures among elderly, the seriousness of the consequence of hip fracture, and how hip protector can reduce the risk of hip fractures. Problems on wearing hip protector like discomfort, physical difficulties and urinary incontinence etc and possible solutions were also introduced to the staff. Other details on wearing hip protectors including wearing regime, wearing and removing hip protector safely, and laundry method were also included in the education program. Finally, the details regarding the implementation of the study including the method of checking and recording compliance as well as fall or fracture incidence etc was also instructed to the staff. The contact persons also brief the other staff on how to properly record and file the related information in the case files of the subjects in this study. Details of the education program were attached in Appendix 2.

2.3.4.3 Education program for elderly subjects

Similar education program as that for the staff was also provided to all the female residents in the four elderly hostels (Appendix 2). The aim of the program was to let the participants more aware of the seriousness of hip fracture and the usefulness

of hip protector in prevention of hip fracture. Purpose and details of this study was also introduced in the program.

2.3.4.4 Fall and fracture risk counseling

After the education program, some assessments related to risk factors of fall and fracture like mobility, functional level etc. were done for each of the participants (described below in session 2.3.5.2). A fall and fracture risk counseling session was provided to each participant. During the session, the personal risks of fall and fracture were explained to each participant and the potential benefit of hip protector was also reinforced.

2.3.4.5 Consent and Ethical approval

Information sheet with detailed verbal explanation on this study (Appendix 3) were provided to the participants. Written consent was obtained from participants who were willing to participate in this study. Consent forms were attached in Appendix 4. Ethical approval of this study was obtained from the Chinese University of Hong Kong and the Hospital Authority New Territories East Cluster Clinical Research Ethics Committee (Reference No.: CRE-2004.331). A copy of ethical approval was attached in Appendix 5.

2.3.4.5 Provision of hip protector and training program on wearing hip protector

All the participants who were willing to wear hip protector received a set of modified hip protector. The set included three pairs of specially designed pants and one pair of pads. The wearing regime of hip protector is 24 hours per day. A practical training session on the use of hip protector was provided. The session included

training on placing the pads correctly into the pocket of the pants, wearing and removing the pants correctly and safely, and the method of laundry for the pants and pads. A leaflet summarizing the use of hip protector was also left for each participant.

2.3.4.6 Follow up and encouragement on the use of hip protector

The four elderly hostels were visited monthly, except the first month that two visits were performed for each hostel. During the visits, short meeting with the contact staff and other responsible staff were made to discuss the problems and solutions in wearing hip protectors among their residents. The staff was also motivated to continue to encourage the residents to wear hip protector. At the first, third, sixth, and twelfth month, the subjects were visited by the investigator to remind them to wear hip protectors. Group discussions were also held to reinforce them on the use of hip protectors, subjects with experience on how the hip protector protected them in fall situation or with positive experience on use of hip protector were also invited to share their experience to others.

2.3.5 Outcome measures

2.3.5.1 Primary outcome

The primary outcome of this study is the compliance rate of hip protector. According to the definition proposed by Kurrle and co-workers, compliance is defined as the wearing of hip protectors in accordance with the recommendations of the study protocol (Kurrle et al. 2004b). Since the wearing regime of hip protector of the present study was 24-hour per day, the compliance of this study is calculated as the percentage of time the hip protector was being worn by the subjects who initially

accept to wear hip protector over the study period. The compliance rate of hip protector was also calculated separately for day time (when subjects were out of bed) and night time (when subjects were in bed), different seasons across the study year and different hostels.

In order to make this study comparable to others, different definitions of compliance in which other studies usually used were also adopted in this study. This included the followings:

(1) Acceptance: calculated as the percentage of potential users who initially agree to wear hip protectors. In this study, it was equal to the percentage of residents fit the inclusion criteria and was selected by the contact persons initially agree to wear hip protector after the education program and the fall and fracture risk counseling session.

(2) Percentage of compliant users over a particular of time: calculated as the percentage of subject still wear hip protector at a particular follow up time. Subjects with zero percent usage of hip protector in an entire month would be regarded as drop-outs.

(3) Protected fall: calculated as the percentage of falls occurred while hip protectors were being worn.

2.3.5.2 Secondary outcomes

The secondary outcomes include falls and related injury rates of subjects, any

adverse effects and feedbacks after wearing hip protectors, confidence against fall in daily activities after wearing hip protector, and any potential factors related to characteristics of the subjects that may affect the compliance of hip protector were also evaluated in this study. The potential factors include the followings:

(1) Presence of fall and fracture history

The presence of fall and fracture history is hypothesized to have positive effect on compliance since people may be easier to realize the adverse effect of the events occurred on their own than those who heard from others. They may be more willing to wear hip protector to protect them from the injury again (Warnke et al. 2004).

(2) Medical co-morbidities

The presence of more medical co-morbidities may have either positive or negative effects on using hip protector. People with more co-morbidities may have lower perceived health (Hornbrook et al. 1996) and thus higher perceived need of hip protector. On the other hand, people with more co-morbidity may experience more difficulties in wearing hip protector which might result in lower compliance.

(3) Presence of urinary incontinence

The presence of urinary incontinence may have negative effect on compliance since people need to change the hip protectors more frequently which would cause extra inconvenience in using hip protector.

(4) Functional level

People with better functional level may associate with higher compliance since

they may be more independent in the changing of hip protector (Kurrle et al. 2004a).

(5) Hand function

Hand function is important for wearing and removing the hip protector and inserting the pads into the pocket of the pants. Thus people with better hand function will be more capable to wear hip protector and may increase the compliance.

(6) Mobility

People with poorer mobility may be more compliant to the use of hip protector since they are at higher risk of fall (American Geriatrics Society et al. 2001).

(7) Cognitive function

People with impaired cognitive function may be less compliant to the use of hip protector since they may not be easily to follow the wearing regime for a number of reasons like not understanding and forgetfulness (Villar et al. 1998).

(8) Fear of falling

People who are less confident in performing activities of daily living without fall may associate with higher compliance in wearing hip protector since hip protector may give them sense of security against fall and fracture (Cameron et al. 2000).

2.3.6 Measurement method

2.3.6.1 Compliance

The compliance of subjects was recorded by the staff of the hostels using

compliance chart (Appendix 6). There were eight episodes for recording the compliance in each study month. The schedule of the episodes was randomly scheduled by the investigator and was kept blinded to all the subjects. The episodes of checking were either at day time (any time when the subjects were out of bed) or night time (just before the subjects were going to bed). There were 4 day time and 4 night time episodes of checking per month. During the checking, the staff was instructed to palpate at the lateral side of the hip of subject to see whether they wore hip protector and recorded on the compliance chart. The investigator visited the hostels monthly to collect the compliance chart and replace a new one for the staff. Four visits by the investigator were made at the first, third, sixth and twelfth month to check the whether the subjects wear the hip protectors correctly.

2.3.6.2 Falls and fractures incidence

Any falls and fractures incidences among the subjects were recorded by the hostel staff at the case files of the subjects. Circumstances of the incidence such as time, place and level of injuries were recorded. Whether the subjects wore hip protector during the incidences were also recorded.

2.3.6.3 Adverse effect and feedback after wearing hip protector

Adverse effect and feedback after wearing hip protector by the subjects were collected through two interviews by the investigator during two visits at the first and sixth month. Feedback from all the subjects who accepted to wear hip protector was collected after the first month of use while the feedback from subjects who continue to wear hip protector after the first month was collected in the sixth month. A standardized test on mobility (described below in session 3.3.6.10) were also

performed in the first visit with the hip protector being worn and compared with that the hip protector were not being worn to investigate if there were any effects of hip protector on mobility. Any feedbacks made by the subjects to the staff were also collected by the investigator during the monthly visit to the hostels.

2.3.6.4 Fear of fall

A standardized evaluation tool, the Activity-specific Balance Confidence Scale (ABC) which was a validated test on confidence against fall in daily living tasks (Miller et al. 2003), was used to evaluate the fear of fall among the subjects. There were 16 activities of daily living in the scale and to each of the activity, the subjects needed to give a score ranging from 1 to 10 representing their confidence against fall in that particular activity, with higher the score, higher the confidence (Appendix 7). The test were performed to all the subjects at the risk counseling session before the provision of hip protectors and were performed to all subjects who were still compliant to wear hip protector at the third month of wearing to see if there was any effect on fear of falling after the wearing of hip protector.

2.3.6.5 Fall and fracture history

Fall and fracture history of subject were asked during the risk counseling session. Subjects were asked whether they had history of fall and the number of falls in the previous year. Fall is defined as any episode of unintentional coming to rest on the ground, floor, or other lower level (Tinetti et al 1993). History of fracture of the subjects after the 50 years old was also asked.

2.3.6.6 Medical co-morbidities

Medical co-morbidities of the subjects were collected by reviewing the case files in the hostel.

2.3.6.7 Presence of urinary incontinence

Presence of urinary incontinence was defined as if there was any episode of leakage of urine unintentionally in the past two weeks. Subjects were asked if they had the condition and whether they need to wear any incontinence pads during the risk counseling session.

2.3.6.8 Functional level

The modified Barthel Index (MBI) was used to assess the independence level of subjects in activities of daily living (Hocking et al. 1999). Independence level at 10 areas of activities of daily were assessed using the scale. The total score range from 0 to 100, with higher the score, higher the independence level (Appendix 8). The assessment was also done during the counseling session.

2.3.6.9 Hand function

The hand functions including power grip, lateral pinch grip power and finger dexterity, which are essential for wearing hip protector, were assessed by the Jamar Dynamometer (Figure 2.8), the Pinch Gauge (Figure 2.9) and the Nine-hole-peg test (Figure 2.10) respectively. The power grip and lateral pinch grip of the dominant hand of the subject were measured in sitting position with shoulder in adduction and elbow in 90° of flexion. The tests repeated for three times to obtain the mean value. The readings of both the test were recorded in kilogram. The Nine-hole-peg test (NHPT)

was done with the standardized testing method described in literature (Mathiowetz et al. 1985). Subjects were required to insert the nine small pegs one by one to the holders with their dominant hand as fast as possible. The score of the test was the time (second) to finish the task required. The hand function tests were performed during the counseling session.

2.3.6.10 Mobility

The mobility of subjects was assessed with the Time Up and Go test (TUG), which is a simple and validated test for mobility (Podsiadlo et al. 1991). Subjects were required to stand from a chair and walk a distance of 3 meters, turn around and walk back to the seat and sit down again. The total time (second) required for finishing the task was recorded. The test were performed during the counseling session and repeated about 1 month later where the subjects were on hip protectors. The needs of walking aids in locomotion were also recorded.

2.3.6.11 Cognitive function

Cognitive function was assessed by the Mini-Mental-State-Examination (MMSE) (Xu et al. 2003). The test were validated for screening of cognitive function like orientation, short term memory, comprehension, following command etc (Appendix 9). The test was also performed during the counseling session.

2.3.7 Sample size calculation

In this study, one group of subject was followed for one year after distributing the hip protector. The compliance rate was the primary outcome of this study. Previous study showed that the mean compliance rate is about 50% (van Schoor et al.

2002). The sample size for calculating 95% confidence interval of the compliance rate will be 95 with standard error of proportion controlled at 0.1 and with statistical power of 0.8. Since there will be 46% of subjects expected not to accept the wearing of hip protector (van Schoor et al. 2002), the total number of subject required for this study was 95/(100%-46%)=176.

2.3.8 Calculation and Statistical method

Repeated measures of ANOVA was used to test the difference in the trend of day time and night time compliance as well as the compliance across different months in the study period. ANOVA was used to test the difference in the acceptance rate and mean compliance rate among different hostels. Difference in characteristics between subjects who accept to wear hip protector and those who did not were tested by the Student's t-test for characteristics in interval scale including age, functional level, cognitive level, hand function, mobility and fear of falling while Pearson's chi square test were used for characteristics in nominal scale including fall and fracture history, medical history, education level, presence of urinary incontinence and use of walking aids. Association between compliance and characteristics of subjects was tested by Pearson's Correlation test for characteristics in interval scale as state above while Spearman's correlation test was used for those in nominal scale as stated above. Spearman's correlation test was also used for testing association between compliance and the feedback from the subjects in using hip protector. Paired sample t-test was used to find out difference in mobility and fear of falling before and after wearing of hip protector by the subjects. All the significant level was set at $p<0.05$. All the statistical calculation was performed with the software SPSS version 13.0 (SPSS Inc, Chicago, IL, USA).

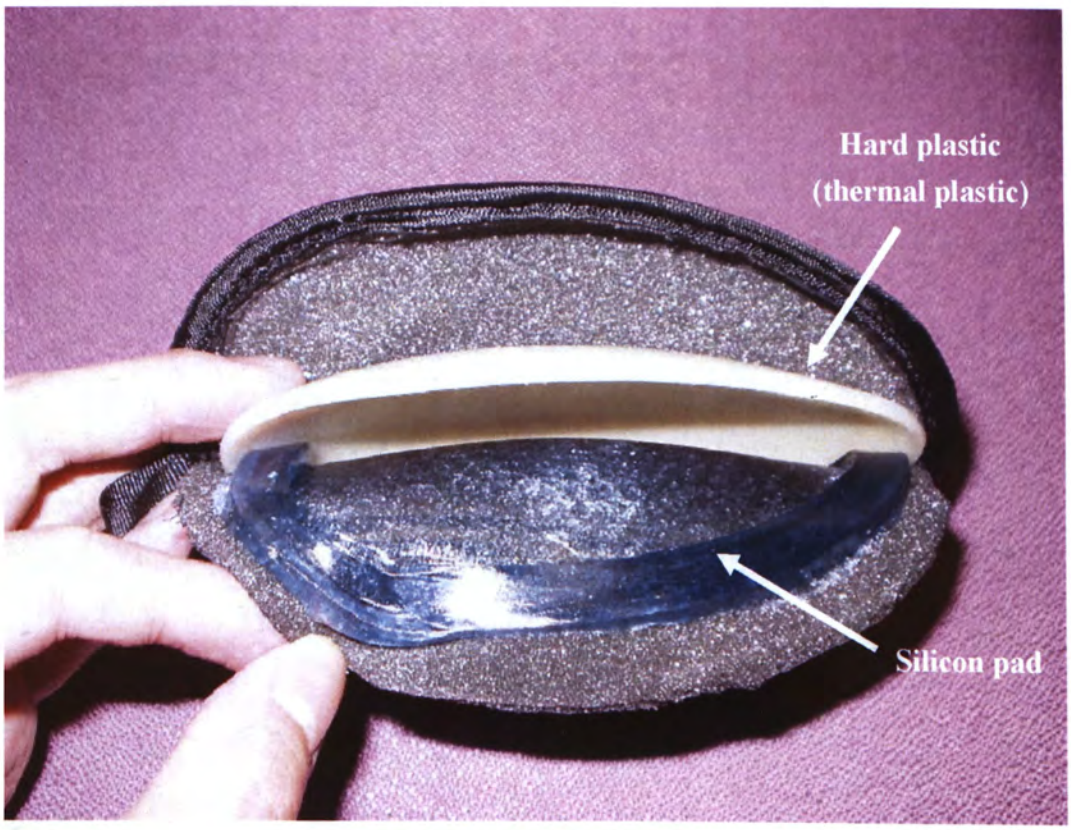
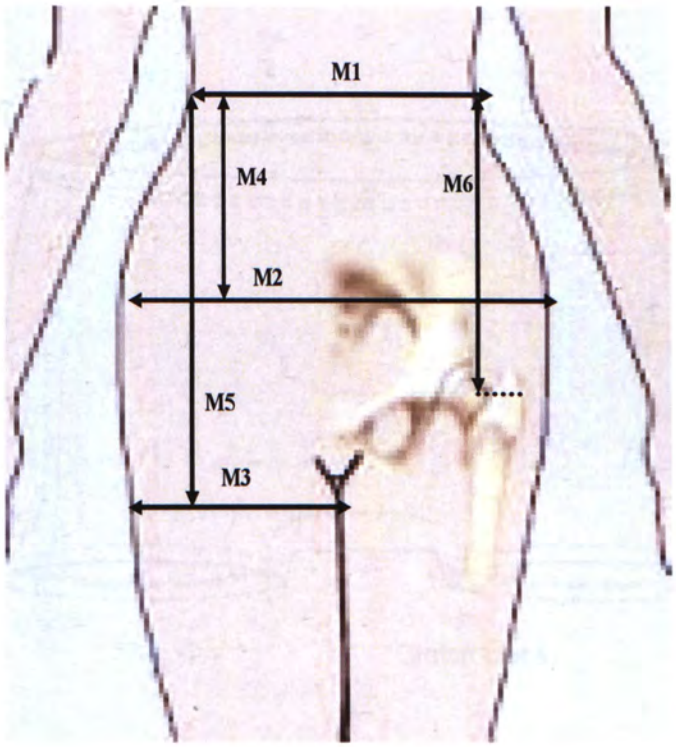


Figure 2.1 Composition of the pad

Figure 2.2 The appearance of the pad



M1: Circumference of waist
M2: Circumference of hip
M3: Circumference of thigh (first round)
M4: Vertical distance between waist and hip
M5: Vertical distance between waist and first round
M6: Vertical distance between waist and greater trochanter

Figure 2.3 Body measurements for making the pants

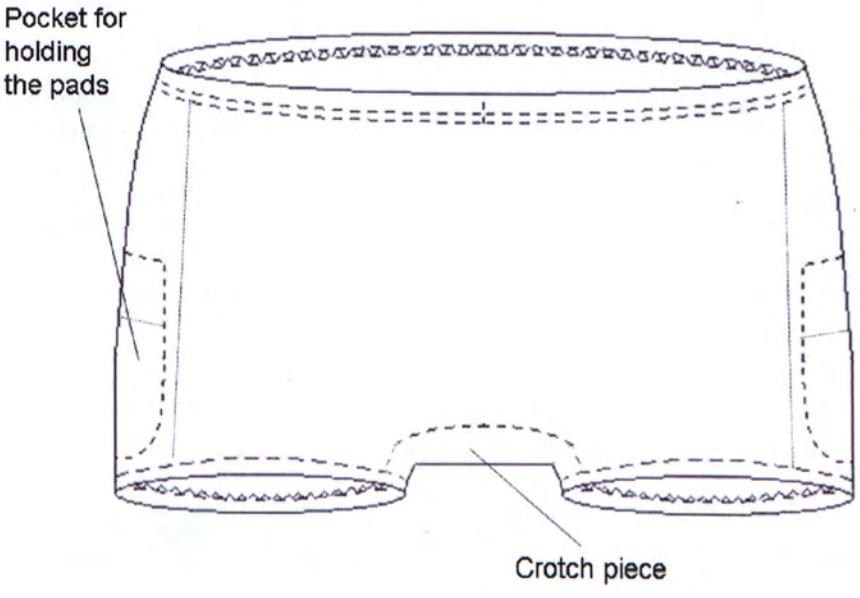


Figure 2.4 Pattern sketch of the pants

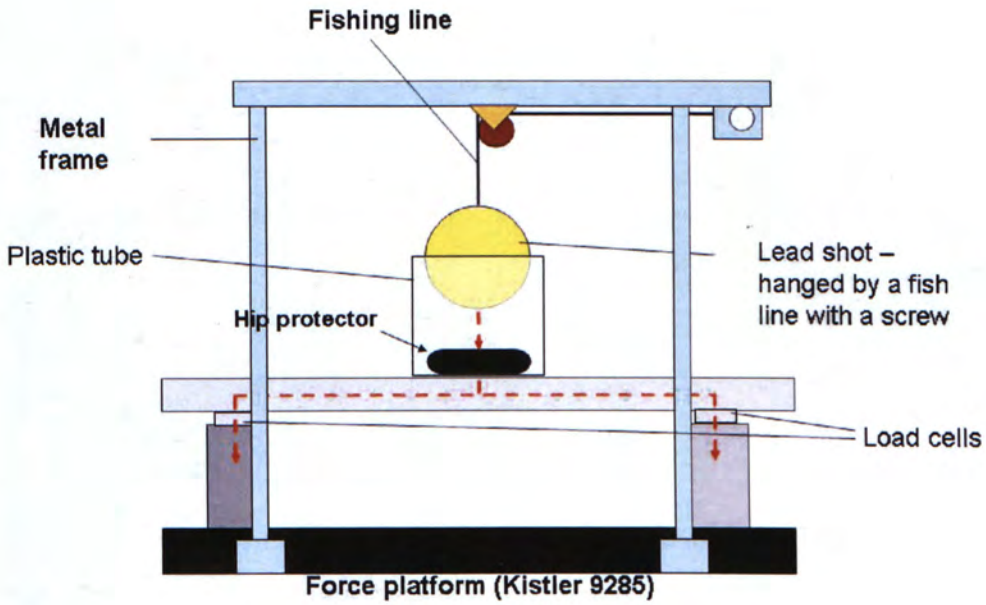


Figure 2.5 Mechanical test set up (schematic sketch)

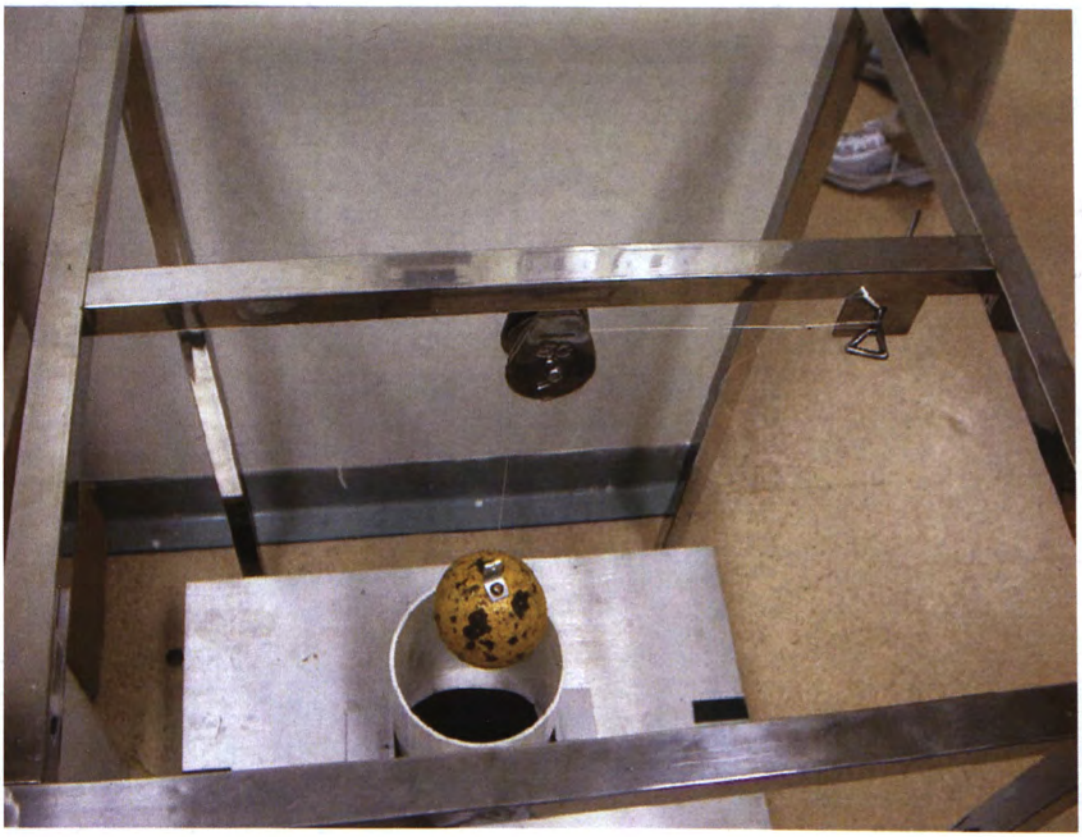


Figure 2.6 Mechanical test set up

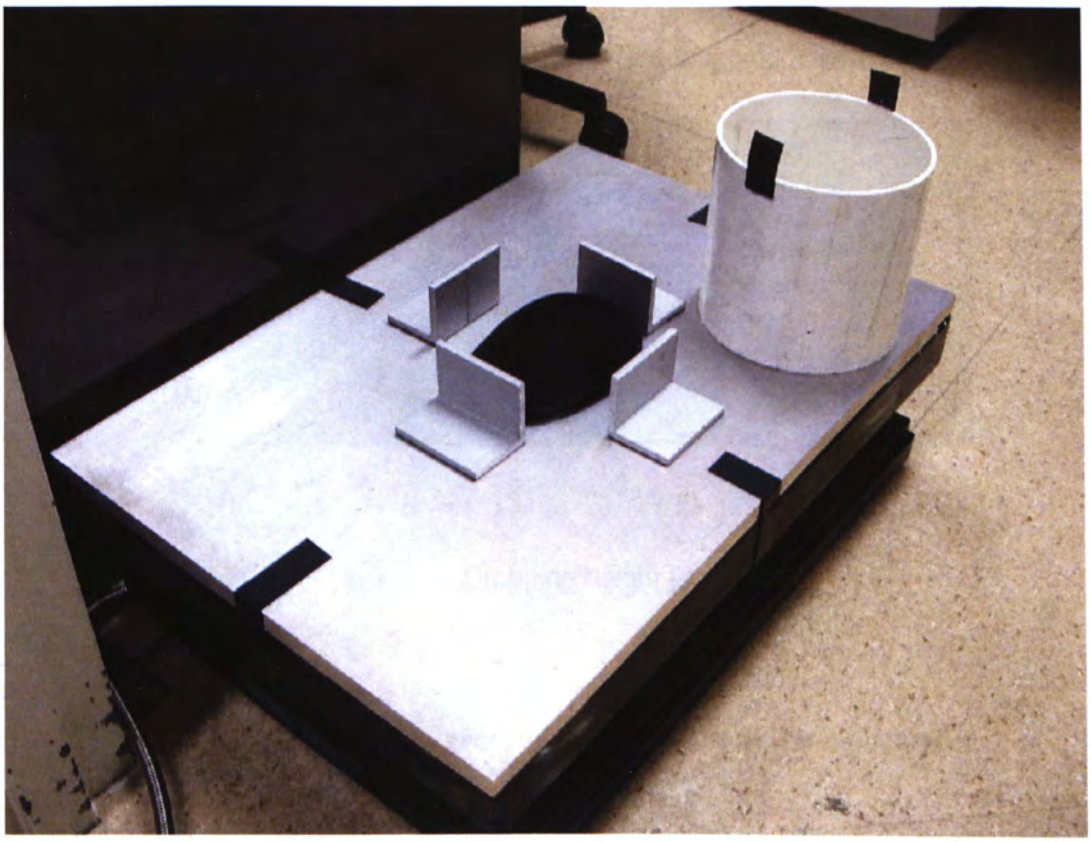


Figure 2.7 the force platform (Kistler 9285, Kistler Instrument Corp, NY, USA)

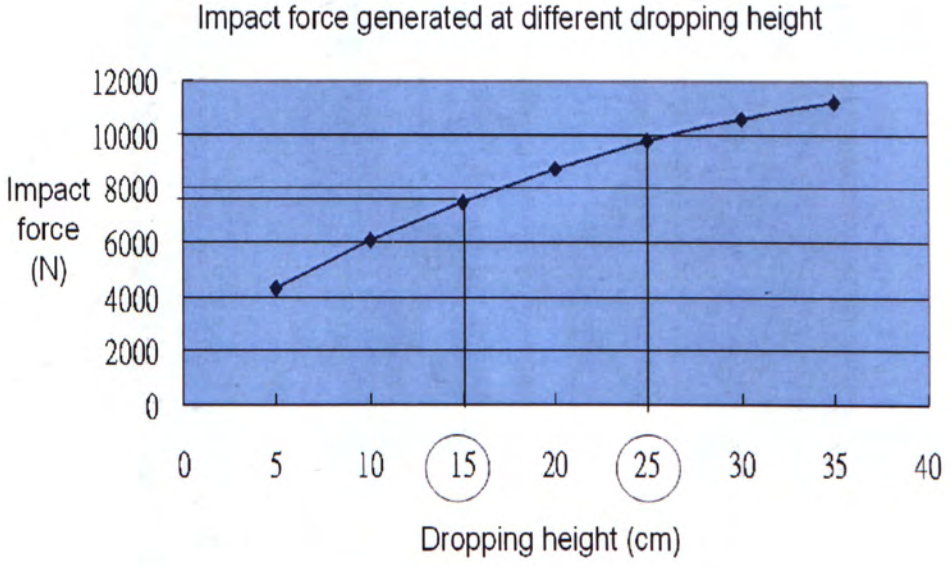


Figure 2.8 Impact force generated at different dropping height

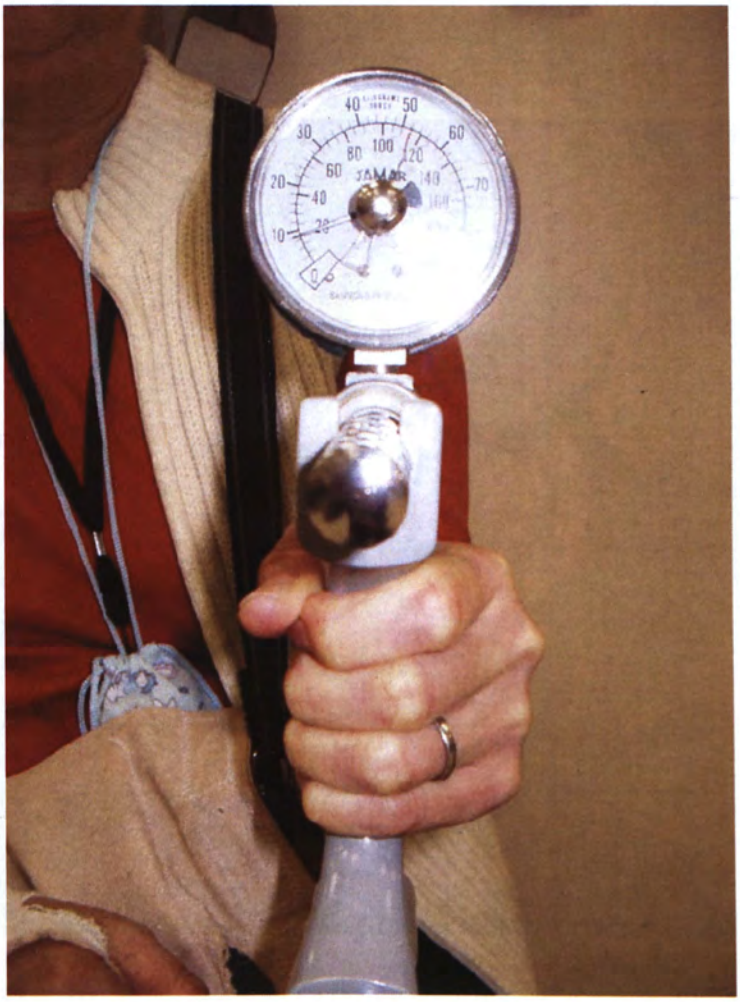


Figure 2.8 Jamar Dynamometer

Figure 2.9 Pinch Gauge

Figure 2.10 Nine Hole Peg Test

Table 2.1 Details of the fabric materials

#1	Name	Bo Lam (寶林)
	Nature	Knitted fabric
	Fiber content	Cotton Lycra
	Color	White
#2	Name	CL-3011 (混王)
	Nature	Knitted fabric
	Fiber content	94% 40° 精棉, 6% 40° Lycra Soft
	Color	Pale Green
#3	Name	CL-2881H (洗水)
	Nature	Knitted fabric
	Fiber content	92% 30s 花灰棉, 8% 45° Lycra Soft
	Color	Green
#4	Name	CL-2987H (洗水)
	Nature	Knitted fabric
	Fiber content	93% 30° Dacron (Coolmax) 花灰, 7% 45° Lycra Soft
	Color	White

Results

III. RESULTS

3.1 Design of hip protector

3.1.1 The design of pants

3.1.1.1 The fabric materials

The four selected fabrics underwent three fabric objectives tests including air permeability test, moisture absorbency test and the dimensional stability test after laundry. The results of the test were summarized in Table 3.1.

For the air permeability test, it was found that the fabric #2 (CL-3011) was the most superior among the four fabrics. The average air permeability of this fabric was 8.7 $cc/cm^2/s$ at 100Pa, i.e., the volume of air penetrated per cm^2 of fabric per second at a pressure difference of 100Pa. The air permeability of this fabric was significantly better than the others (p values <0.001).

For the moisture absorbency test, fabric #4 (CL-2987H) showed the best performance among the four. It took an average of 1.26 second to absorb the water droplet completely and was significantly faster than the others ($p < 0.001$).

Lastly for the dimensional stability test, fabric #4 (CL-2987H) again, showed the least percentage of shrinkage after repetitive laundry. The mean percentage of shrinkage in the direction parallel to the width and length of fabric were only 1.52% and 0.56% respectively, which were both significantly lower than that of other fabrics

($p<0.001$).

In consideration of the result of the fabric test, fabric #4 (CL-2987H) was selected as it had the best performance in the moisture absorbency test and showed the best dimensional stability after laundry. It was also the second best in air permeability test. Although fabric #2 was better than fabric #4 in air permeability, it performed poorly in the other tests. Therefore, fabric #2 was not chosen finally.

3.1.1.2 The size of the pants

There were 69 volunteers recruited for the measurement. All the volunteers were female with mean age of 78.1 (SD: 8.1).

The mean waist circumference among the subjects was 85.9cm (SD: 9.2cm), the 95% confidence interval was between 82.85 to 87.59 cm. The range of the circumference was from 72 to 109 cm (Figure 3.1).

The volunteers were divided equally into five categories according to their waist circumference. Subjects with waist circumference 79 cm or below belong to group XS, 80 to 86 cm belong to group S, 87 to 93 cm belong to group M, 94 to 100 cm belong to group L, and 101 cm or above belong to group XL. The measurements of each group of volunteers were used to develop the sizes of the pants from XS to XL. The details of the measurements for each group was summarized in Table 3.2.

The mean vertical distance between the waist and the greater trochanter among all the volunteers was 16.3 cm (95% CI: 15.7 – 16.9 cm). The inter-quartile range was

15 – 18 cm and the 10^{th} to 90^{th} percentile range was 14 – 19 cm. The mean value was used as the reference point for locating the pocket which holds the pads on the pants. There was no significant difference of the location of the greater trochanter among the different size groups (p=0.87). Therefore the location of the pocket on the pants was the same across different sizes. The 10^{th} to 90^{th} percentile range (5 cm range) of the greater trochanter was used as the reference in determining the length of the pads in order to make sure the pads were able to cover the greater trochanter for most of the users.

3.1.2 The design of pads

3.1.2.1 Thickness of silicon padding

The three prototypes with 12mm, 7mm and 2mm thickness silicon padding respectively were tried by the volunteers. All the three volunteers reported the feeling of discomfort by the pressing of the 2mm prototype particularly on bed but none of them reported the same pressing by the 7mm and 12mm prototype. For the 12mm prototype, all the users reported that it was too heavy and made the pants dropped so that they needed to pull up the pants frequently to restore the correct position. These problems, however, were not found in the 7mm prototype.

3.1.1.2 Dimension of the hard shield

According to the recommendation by Kannus and coworkers (Kannus 1999), a 1.5 cm gap was left between the inner side of the pad and the skin covering the greater trochanter, with the addition of the thickness of the pad (7mm silicon pads, 3.2mm Orfit hard shield), the maximum height of the pads were about 2.5cm, which was the

same as the reported model with the lowest height (Mills 1993, Kannus 1999, Weiner 2002). For the pads to be covered correctly right above the greater trochanter, there should be at least 5 cm length in the longitudinal axis of the convex area of the pad, which had at least 1.5 cm above the skin, according the results of the anthropometric measurements (results presented above at session 3.1.1.2). In order to fit the body figure of the hip, the pad was designed with a curvature which was similar to that of the hip, with height gradually decrease along both the transverse axis and the longitudinal axis from the convex right beyond the greater trochanter. The shape of the pads was similar to an oval shape with the proximal part more rounded and the distal part comparatively sharper. There was a convex at approximately one third alone the longitudinal axis from the proximal side. The maximum length and width was 14 cm and 9 cm respectively. The shape and dimensions of the pads were illustrated in Figure 3.2 to 3.4.

3.2 Mechanical test on force attenuation properties of the pads

In order to provide the adequate force which simulated the low impact fall and the high impact fall, the height of the lead shot was set to 0.15m and 0.25m respectively. The mean impact force provided by the high impact was 10315N (SD: 91N. The 95% confidence interval was between 10295N and 10371N (Figure 3.5) and the precision error in coefficient of variation is 0.9%. On the other hand, the mean impact force provided by the low impact was 7164N (SD: 158N, 95% CI: 7066N –7262N) (Figure 3.6). The precision error in coefficient of variation is 2.2%.

3.2.1 Impact force

The test results in the force attenuation properties of the prototypes under the

high impact and the low impact were summarized in Figure 3.7 and 3.8 respectively.

With the mean impact force generated at 7164N in the low impact condition, the three prototypes attenuated the impact forces to 739N (2mm prototype), 467N (7mm prototype), and 311N (12mm prototype) on average. There were significant difference in the force attenuation properties among the three different prototypes in the low impact condition ($p<0.001$). The 12mm thickness prototype provided the best force attenuation property.

In the high impact condition where the mean impact force was as high as 10315N, the 2mm prototype attenuated the impact force to 1125N, and accordingly, the 7mm prototype to 703N, and the 12mm prototype to 487N. There were also significant difference in the force attenuation properties among the three different prototypes ($p<0.001$), with thicker the pads, more powerful in force attenuation. Figures 3.9 to 3.10 illustrated the force attenuation properties of the 7mm prototype under both the high impact and low impact conditions.

When compared with the fracture threshold of the proximal femur of older ladies, which was found to be 3100N (±1200N) in a large scale in vitro biomechanical study (Cheng 1997), all the three prototypes attenuated the impact force to a significantly lower level in both the low impact and high impact condition. The 12mm and 7mm thickness prototypes even reduced the impact force to a level that was 2 standard deviations below the mean fracture threshold of the proximal femur in both the impact conditions.

The force attenuation properties of the pads in consecutive impact was summarized in Figure 3.11 to 3.16. It was found that there was no significant difference on force attenuation properties of the same pad among consecutive impacts in both the high and low impact condition.

3.2.2 Impact duration

The duration of impact under different impact conditions were summarized in Table 3.3. The mean duration of impact in the low impact condition was 2.2ms. With the application of the three prototypes, the duration of impact increased accordingly, to 16.4ms for the 2mm prototype, 25.8ms for the 7mm prototype and 38.4 ms for the 12mm prototype. On the other hand, the mean duration of impact in the high impact condition was 2.2ms, with the application of the prototypes, the duration of impact increased accordingly, to 17.2ms for the 2mm prototype, to 24ms for the 7mm prototype, and to 36ms for the 12mm prototype.

There was significant increase in the impact time after the application of the three prototypes in both the high and low impact conditions (all $p<0.001$). However, there was no significant difference found among different impacts of the same pad in both the low and high impact conditions.

3.2.3 Selection of the prototype

After the mechanical test and the previous feedback from the volunteers, the 7mm prototype was finally selected for the compliance study since it has adequate force attenuation properties and the least complaints on trial wearing.

3.3 Compliance study

3.3.1 Demographics

There were 4 elderly hostels enrolled in this study. The characteristics of the hostels were summarized in Table 3.4. There were a total number of 179 subjects matched the inclusion criteria of this study. The mean age of the subjects were 82.2 (±6.0). Majority (73.2%) did not receive any formal education. There were about 16% of the subjects had history of fall in the previous year and there were 16% of them had history of fracture since the age of 50. Details of the characteristics among subjects in each hostel were summarized in Table 3.5 (demographics and fall and fracture history) and Table 3.6 (functional levels).

3.3.2 Primary outcome

3.3.2.1 Initial acceptance rate

Table 3.7 summarized the acceptance rate among all the subjects and in different hostels. Among the 179 subjects, 118 accepted to wear hip protector after the education session on hip protector and risk counseling session. The initial acceptance rate was 65.9%. The acceptance rate varied from 53% to 90% across the four elderly hostels (Pearson Chi-Square: 11.22, p=0.011).

3.3.2.2 Compliance rate

Figure 3.17 summarized the compliance of subjects in wearing hip protector across the study period. The average compliance rate of each of the 12 study months ranged from 18% to 66%. The compliance rate was the highest in the first two months

(December and January). It dropped to a trough in the ninth month (August) and increased back to about 35% in the last month of the study. The pattern of day time compliance rate was similar to that of the night time across the study period. There was no significant difference between the trend of the day and night time compliance ($p=0.85$). However, the compliance rate was found to significantly vary across the study period ($p<0.001$). The compliance rate was above 50% in December to March, between 30% to 50% in April, May and November, and below 30% in June to October.

Table 3.8 summarized the mean compliance of hip protector across different hostels. The mean compliance of hip protector across the study period was 40.6% (day time), 40.1% (night time) and 40.4% (whole day). Among the hostels, Hostel Y had the highest compliance rate in the day time compliance (49%), night time compliance (46.3%) and whole day compliance (47.5%). On the other hand, Hostel K had the lowest in day time (27.6%), night time (28%) and whole day (27.8%). However, the compliance rates in day time ($p=0.23$), night time ($p=0.36$) and whole day ($p=0.29$) were not significantly different across different hostels.

Most of the subjects wore the hip protector correctly as checked in the visit made by the investigator. There were only 3 subjects wore the pants with front-back inversed during the first visit. Further education was provided for discriminating the front and back of the pants. All the subjects wore the hip protector correctly in the second to fourth announced visit.

3.3.2.3 Percentage of people wearing hip protector across the study period

The number of subjects wearing hip protector across the study period was summarized in Figure 3.18. There were totally 118 subjects initially accepted to wear hip protector. At the end of the third month (Feb), 84 (71.2%) subjects were still wearing hip protector. The number of subjects wearing hip protector became relatively steady in the following two months (Mar and Apr) but dropped sharply in May to only 51 (43%). The number of drop-outs continued to increase in the following months and the number of subjects still wearing hip protector at the end of August was only 26 (22%). However, there were more subjects resumed to wear hip protector in the last three months of the study. At the end of the study, there were still 46 (39%) subjects continued to wear hip protector. There were 3 subjects discharged from the hostels (2 in the forth month and 1 in the eleventh month) and one subject passed away in the second month of the study.

3.3.2.4 Percentage of protected fall

There were totally 23 falls record among the 118 subjects who initially accepted to wear hip protector over the study period. Among the falls, 10 of them occurred while hip protector was being worn. The percentage of protected fall was 43.5%.

3.3.3 Secondary outcomes

3.3.3.1 Fall and related injury among the subjects in the study period

The incidence of falls and related injuries was summarized in Table 3.9. There were totally 34 falls occurred among the subjects within the follow up period. The incidence of fall was 19.0 falls per 100 person year. There were totally 4 head injuries,

2 hip fractures and 5 other fractures occurred as result from these falls.

The incidence of fall for subjects who did not accept to wear hip protector was 18.06 per 100 person year. There were 1 (9.1%) hip fracture and 3 (27.3%) other fractures resulted from these falls.

Among the subjects who showed acceptance to wear hip protector, the mean compliance rate over the study period was 40.4% while the non-compliance rate was 59.6%. According to the following formulae, the incidence of protected falls and unprotected fall was 18.48 and 20.98 per 100 person year respectively.

Incidence of protected fall:

Number of falls / (Number of subjects*average compliance rate)

Incidence of unprotected fall:

Number of falls / (Number of subjects*(1 - average compliance rate))

Among the protected falls, only one (10%) non-hip fracture occurred. There was no hip fracture resulted. On the other hand, there were one (7.7%) hip fracture and one (7.7%) non-hip fracture as resulted from the unprotected fall.

3.3.3.2 Reasons for non-acceptance

A number of reasons were given by the subjects for not accepting the wearing of hip protector. The reasons were summarized into seven categories: (1)clumsy, (2)extra pants, (3)no need, (4)design, (5)appearance, (6)no reason, and (7)others (Figure 3.19).

The descriptions of these categories were summarized as follow:

(1) Clumsiness: clumsy in positioning the pads, the wearing and removing of the pants

(2) Extra pants: need to wear additional pants

(3) No need: not necessary as self perceived risk of fall or fractures was low

(4) Design: did not like the fabric materials or the design of the pants

(5) Appearance: did not like the appearance after wearing or bulkiness of the pads

(6) No reason: no specific reason was given for non acceptance

(7) Others: included concerning the laundry problems, discomfort, heat wave, forgetfulness etc.

The most common reason for not accepting to wear hip protector was the consideration of wearing a pair of extra pants (the hip protector). Fifteen out of the 61 subjects said there was no need for themselves to wear hip protector and about one fifth of subjects did not like the design of the hip protector and said it was clumsy in positioning the pads and wears the hip protector (Figure 3.19).

In reviewing the difference of the demographics and fall history (Table 3.10) and functional levels (Table 3.11) between the subjects who accepted to wear hip protector and those who did not, only the characteristics of with 3 or more comorbidities and better performance in activities of daily living associated positively with the acceptance of hip protector at marginal significant level. Other potential determinants of acceptance of hip protector included with recurrent fall history in the previous year, with history of fracture since the age of 50 and with better education level.

3.3.3.3 Feedback in using hip protector

There were some positive or neutral feedbacks provided by the subjects in both the first month follow up (Figure 3.20) and the sixth month (Figure 3.21). Most of the positive feedback related to the feeling of the hip protector as comfortable to wear (12%) and the gaining of confidence against fall after using the hip protector (29%). There were 24% of subjects said they regarded the hip protectors as usual under garment. However, the positive feedback collected at the end of the sixth month decreased, particularly fewer subjects feeling the hip protectors were more comfortable (8.2%) and regarded the hip protectors as usual under garment (12.4%).

Negative feedbacks from the subjects were summarized in Figure 3.22 (first month) and Figure 3.23 (sixth month). Tightness of the pants (32%) and extra effort for removing and dressing the pants (24%) were the major negative feedbacks in the first month. However, in the sixth month, the major negative feedback in using the hip protector was feeling too hot in wearing (58%).

3.3.3.4 Factors associated with compliance and non-compliance (feedback in wearing hip protector)

Association between the feedback of subjects in using hip protector and compliance were summarized in Table 3.12. It was found that the feedback of experiencing the hip protector as comfortable to wear ($p<0.01$) and gaining confidence against fall in activities of daily living after wearing hip protector ($p<0.01$) were associated with compliance. On the other hand, factors associated significantly with non-compliance included feeling of discomfort as a result of tightness of the pants ($p<0.01$) and complaining the hip protector was too hot to wear ($p<0.05$).

Complaining discomfort caused by pressing from pads while wearing the hip protector also associated with non-compliance with marginal significance (p=0.067).

3.3.3.5 Factors associated with compliance and non-compliance (subject characteristics)

Association between the compliance rate of hip protector and the characteristics of subjects were summarized in Table 3.13. All the characteristics associated weakly with compliance and non-compliance. The correlation coefficients range from 0.015 to 0.167 for compliance and 0.006 to 0.121 for non-compliance. All these association did not reach significant level.

3.3.3.6 Effect on mobility after wearing hip protector

There mean duration for subjects to finish the time up and go test before and after the wearing of hip protector was 15.1 (±7.05) second and 14.8 (±8.16) second respectively. There was no significant difference between the two durations (p=0.39).

3.3.3.7 Fear of fall after wearing hip protector

There was significant increase in the total score of the Activities-specific Balance Confidence Scale among the subjects after the wearing of hip protector (p=0.01). Itemized improvement was also found (Table 3.14). There was significant increase in the score of the item "Walking around the house" (p<0.001) and the item "Getting in / out of a bus" (p=0.04).

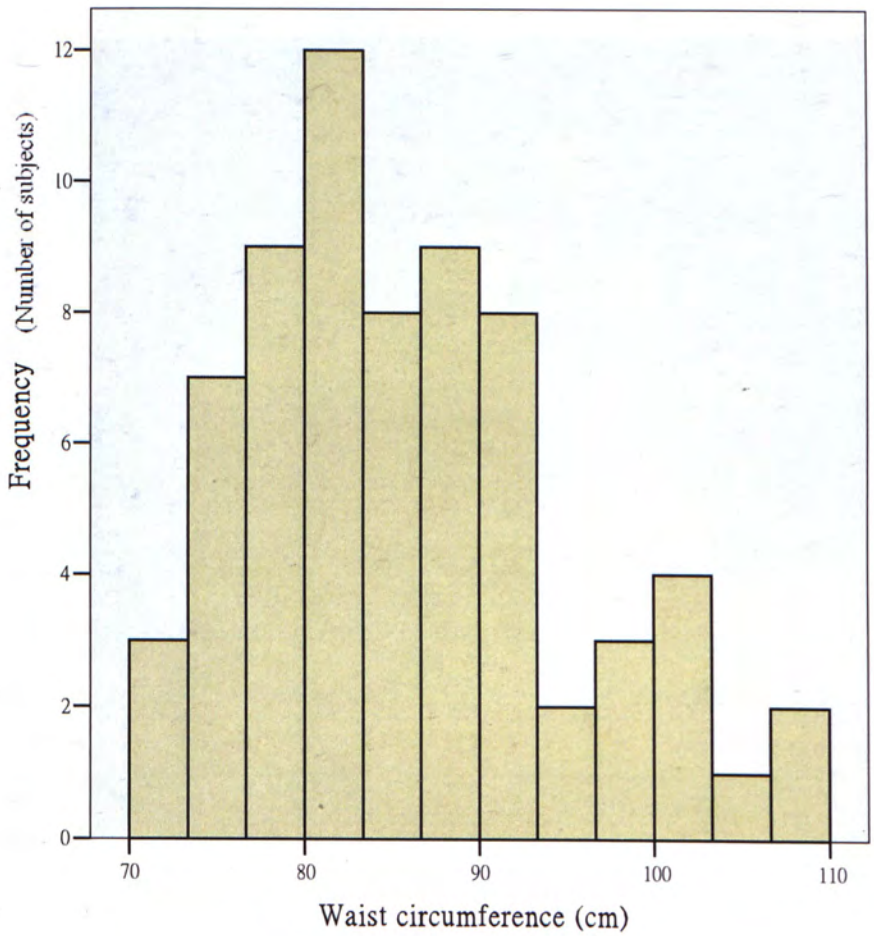


Figure 3.1 Histogram of the waist circumference of the volunteers

Figure 3.2 Shape of the pad

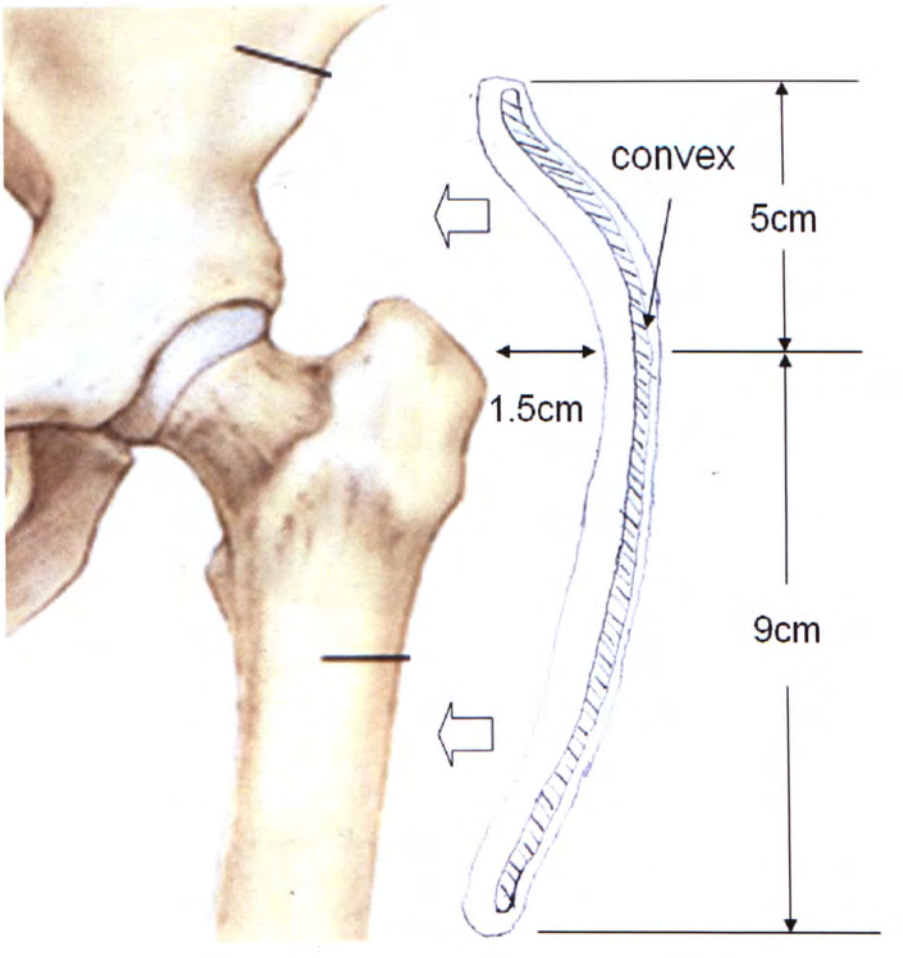


Figure 3.3 Schematic sketch of the sagittal view of the pad

Figure 3.4 Dimensions of the pad

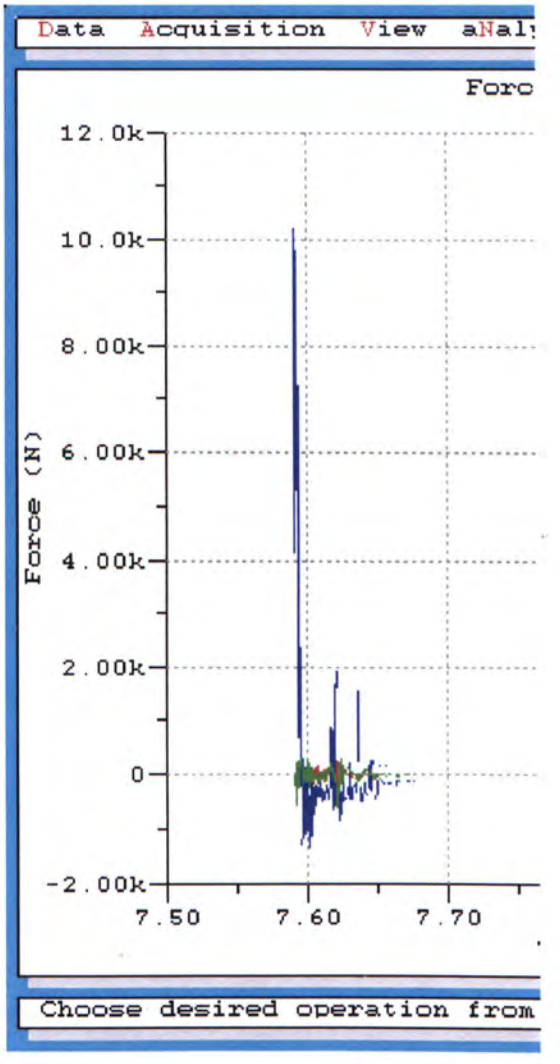


Figure 3.5 Impact force simulated by the lead shot under high impact* condition

*impact force as a result from lateral fall landing on hip with muscle in contraction state

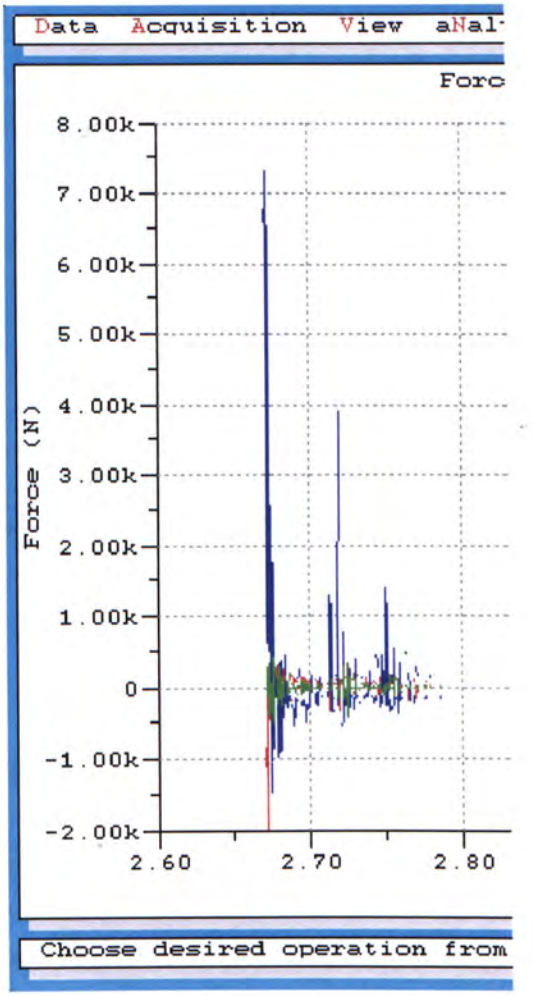


Figure 3.6 Impact force simulated by the lead shot under low impact* condition

*impact force as a result from lateral fall landing on hip with muscle in relax state

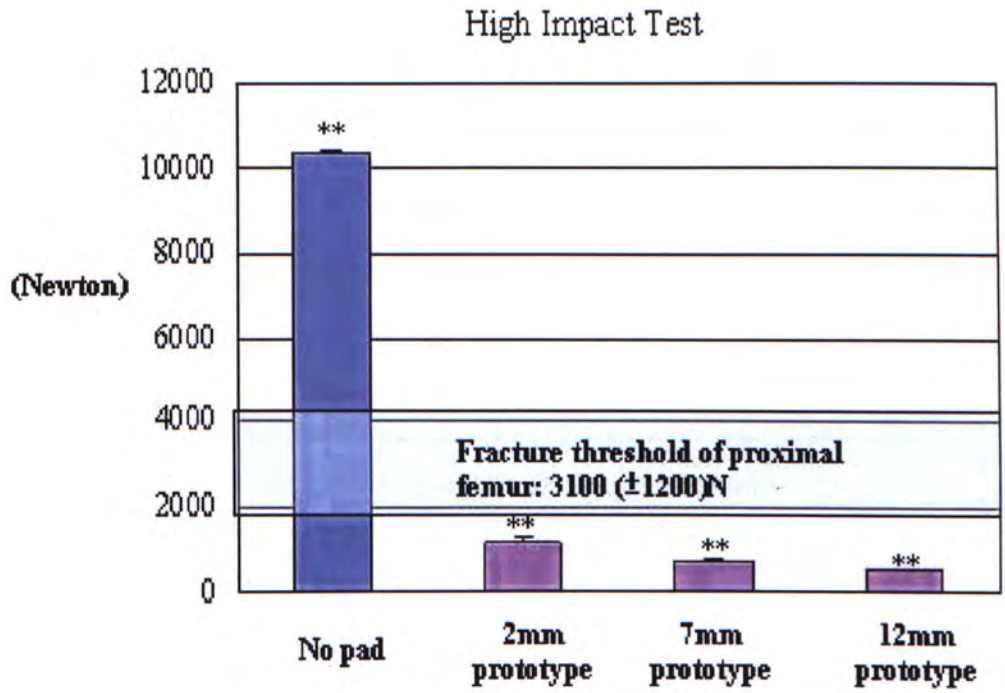


Figure 3.7 Force attenuation properties of the prototypes under high impact condition.

** Value significantly differed from the fracture threshold of proximal femur at p=0.01 level

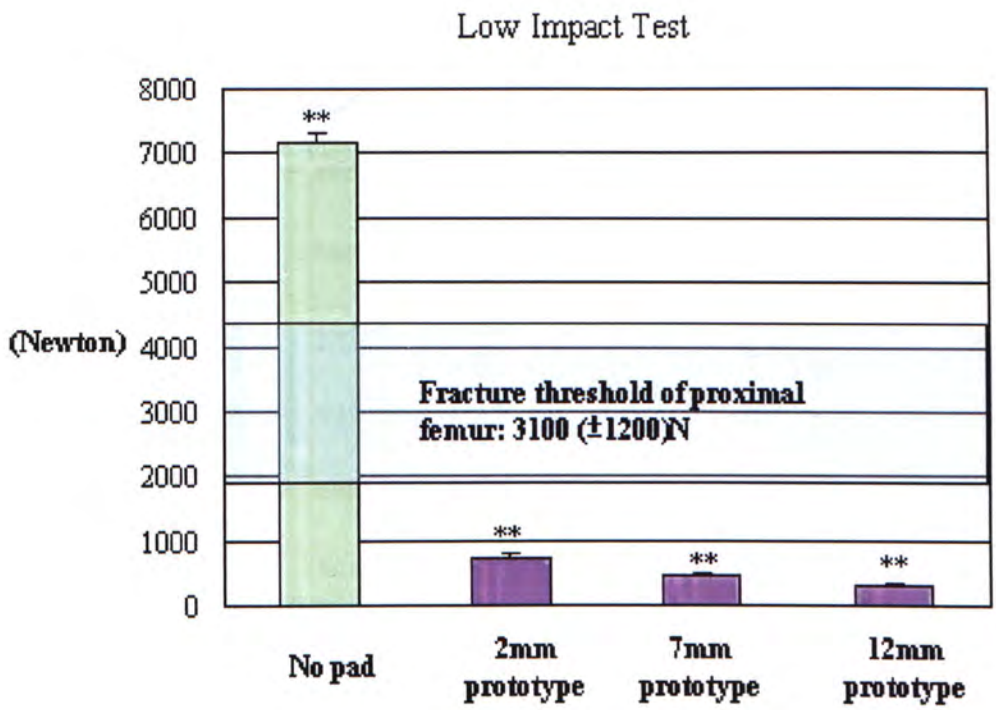


Figure 3.8 Force attenuation properties of the prototypes under low impact condition.

** Value significantly differed from the fracture threshold of proximal femur at p=0.01 level

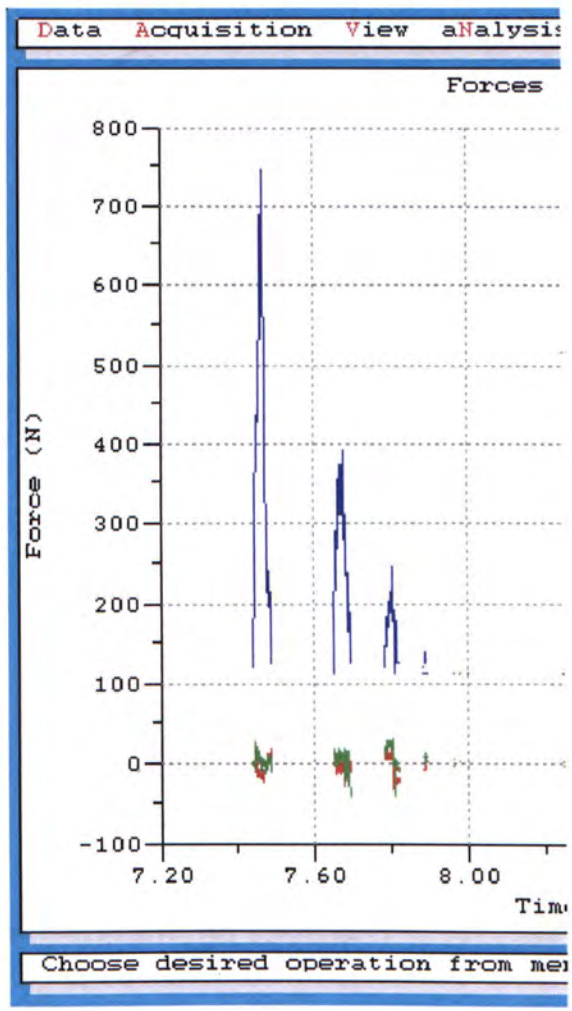


Figure 3.9 Impact force after the attenuation by the 7mm prototype under high impact condition

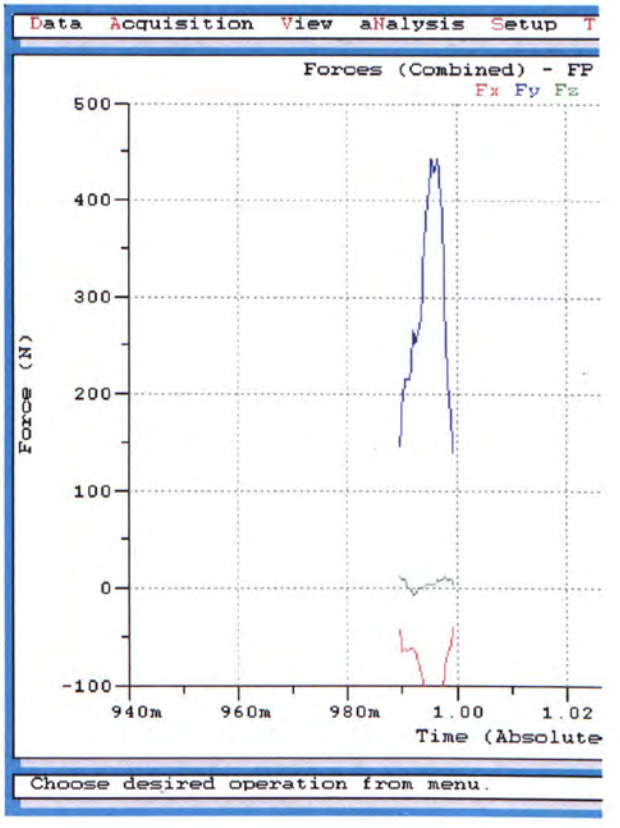
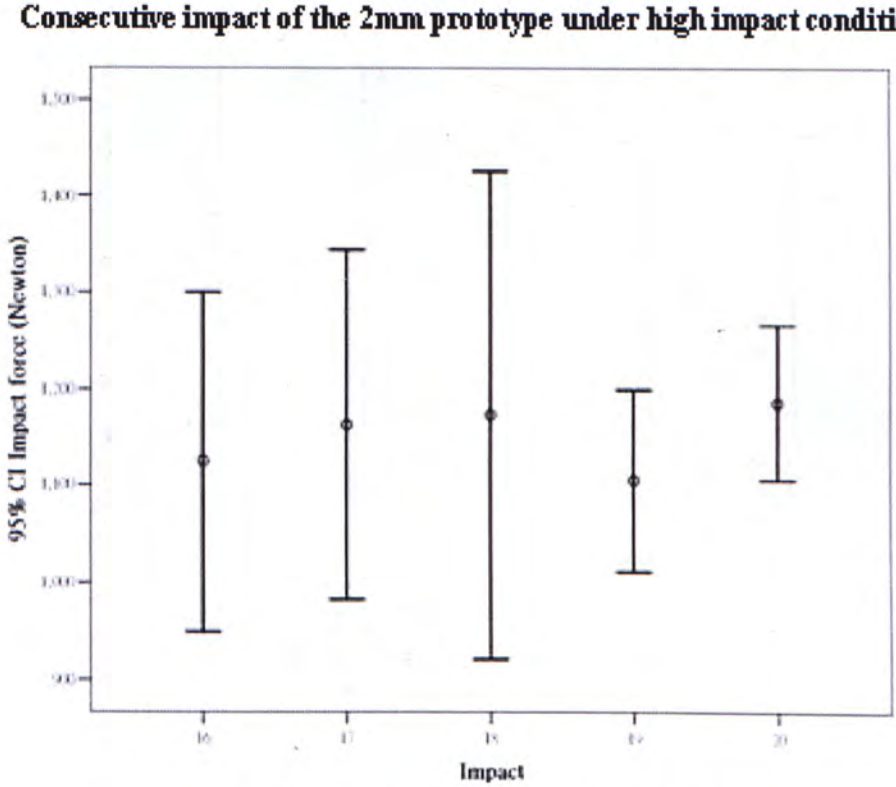
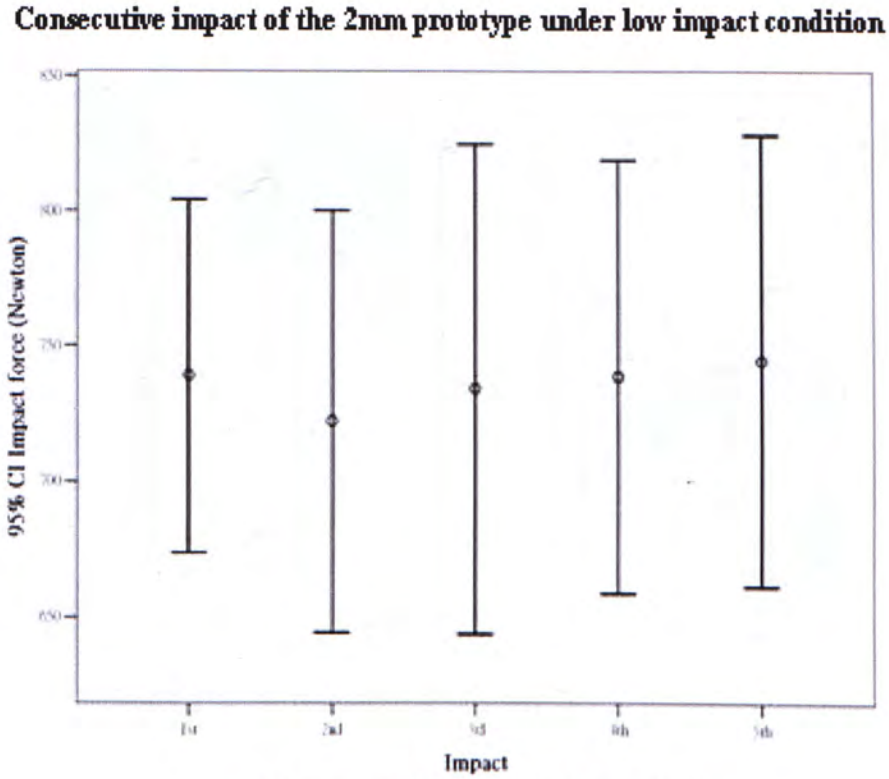


Figure 3.10 Impact force after the attenuation by the 7mm prototype under low impact condition



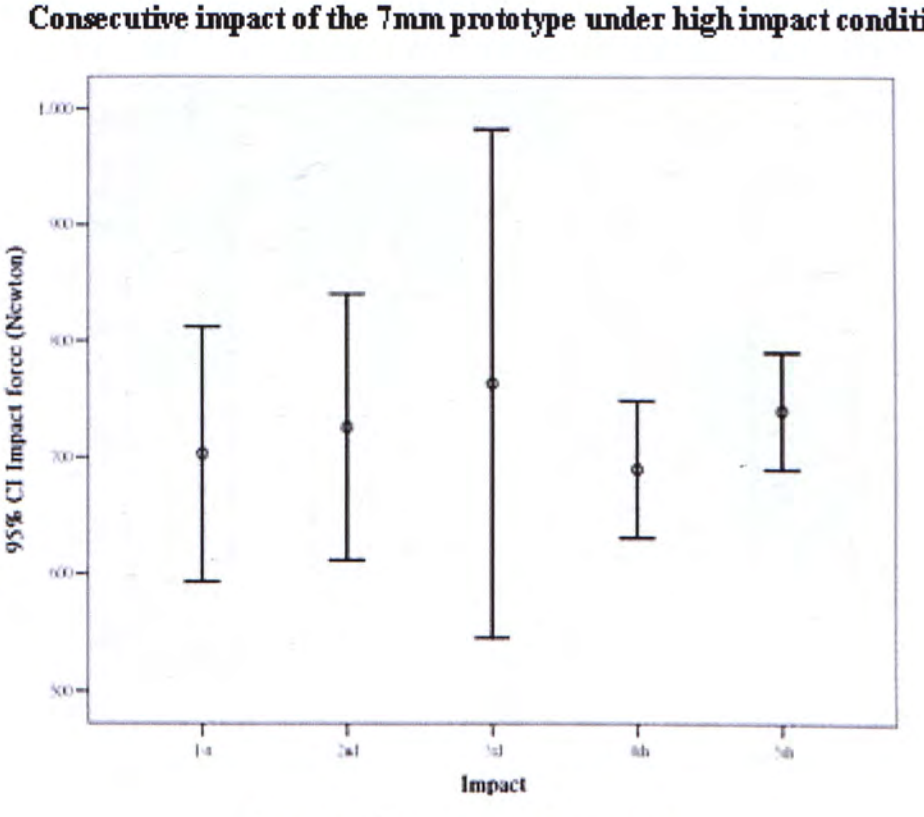
(Mean and SD of tests for 5 samples)

Figure 3.11 Force attenuation properties of the 2mm prototype in five consecutive impact under high impact condition



(Mean and SD of tests for 5 samples)

Figure 3.12 Force attenuation properties of the 2mm prototype in five consecutive impact under low impact condition



(Mean and SD of tests for 5 samples)

Figure 3.13 Force attenuation properties of the 7mm prototype in five consecutive impact under high impact condition

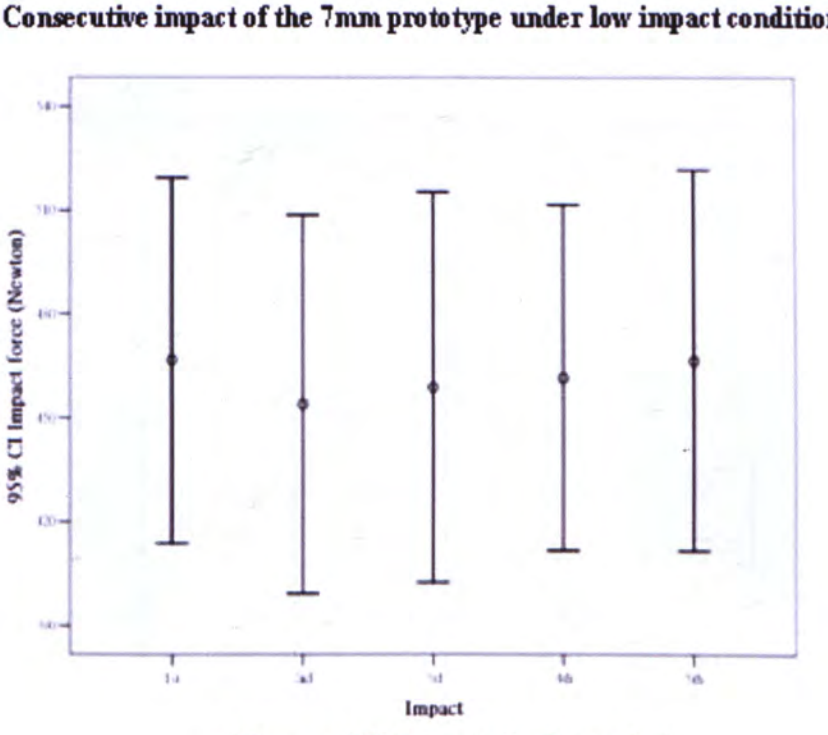
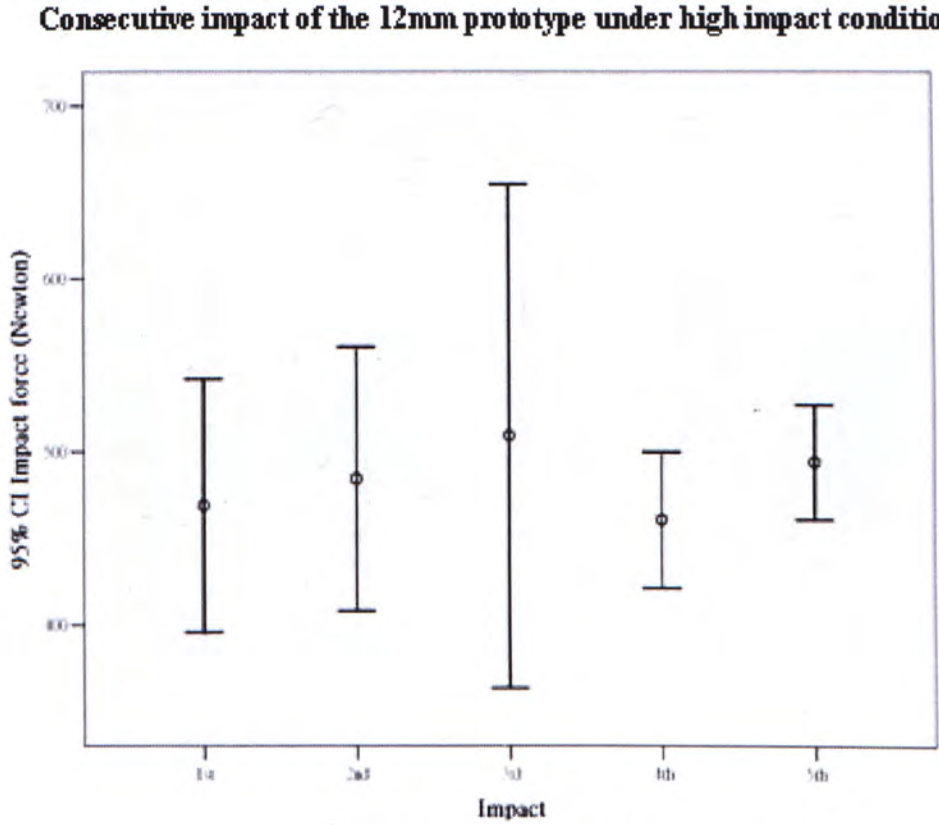


Figure 3.14 Force attenuation properties of the 7mm prototype in five consecutive impact under low impact condition



(Mean and SD of tests for 5 samples)

Figure 3.15 Force attenuation properties of the 12mm prototype in five consecutive impact under high impact condition

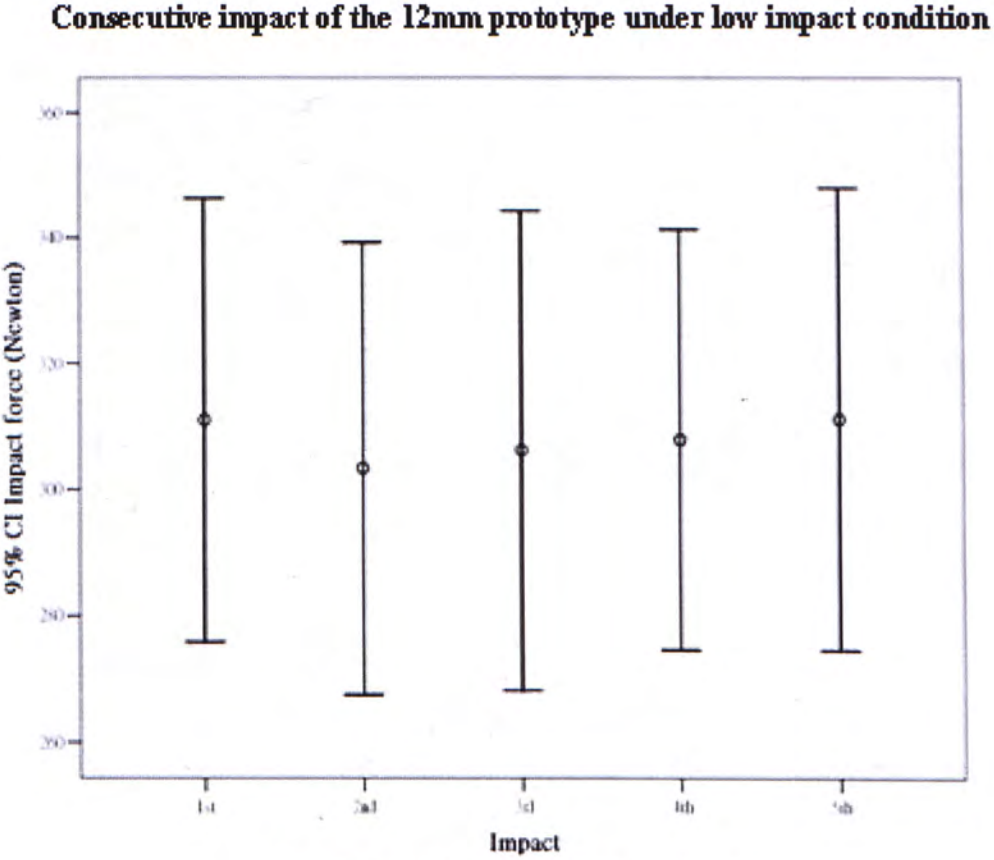
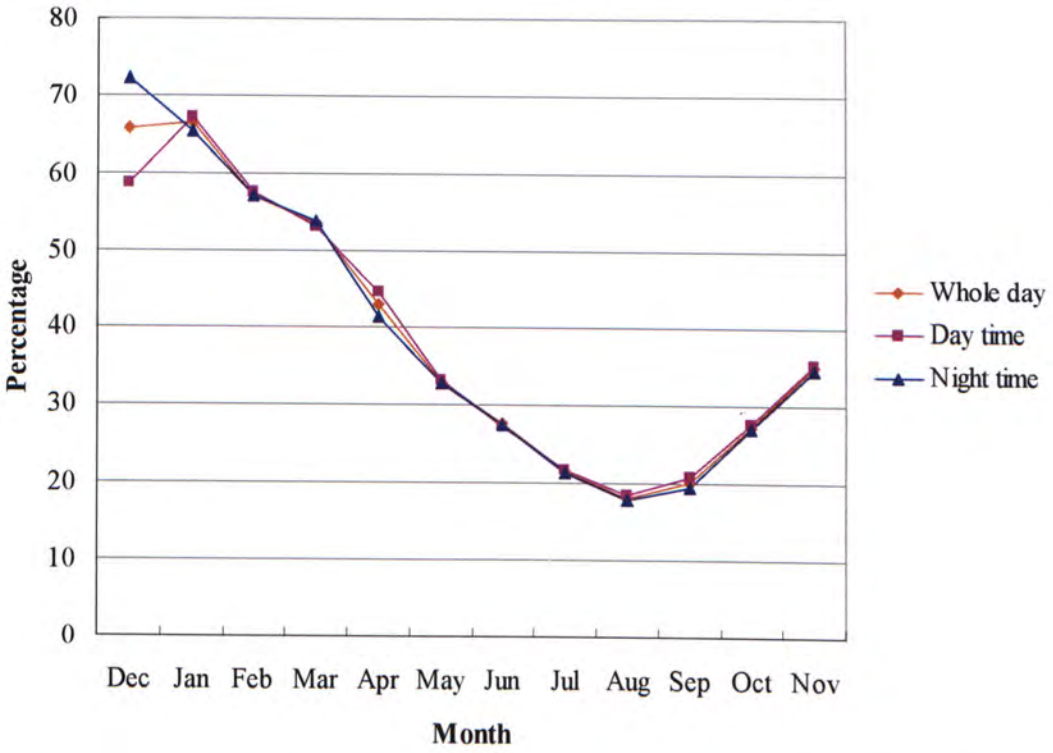


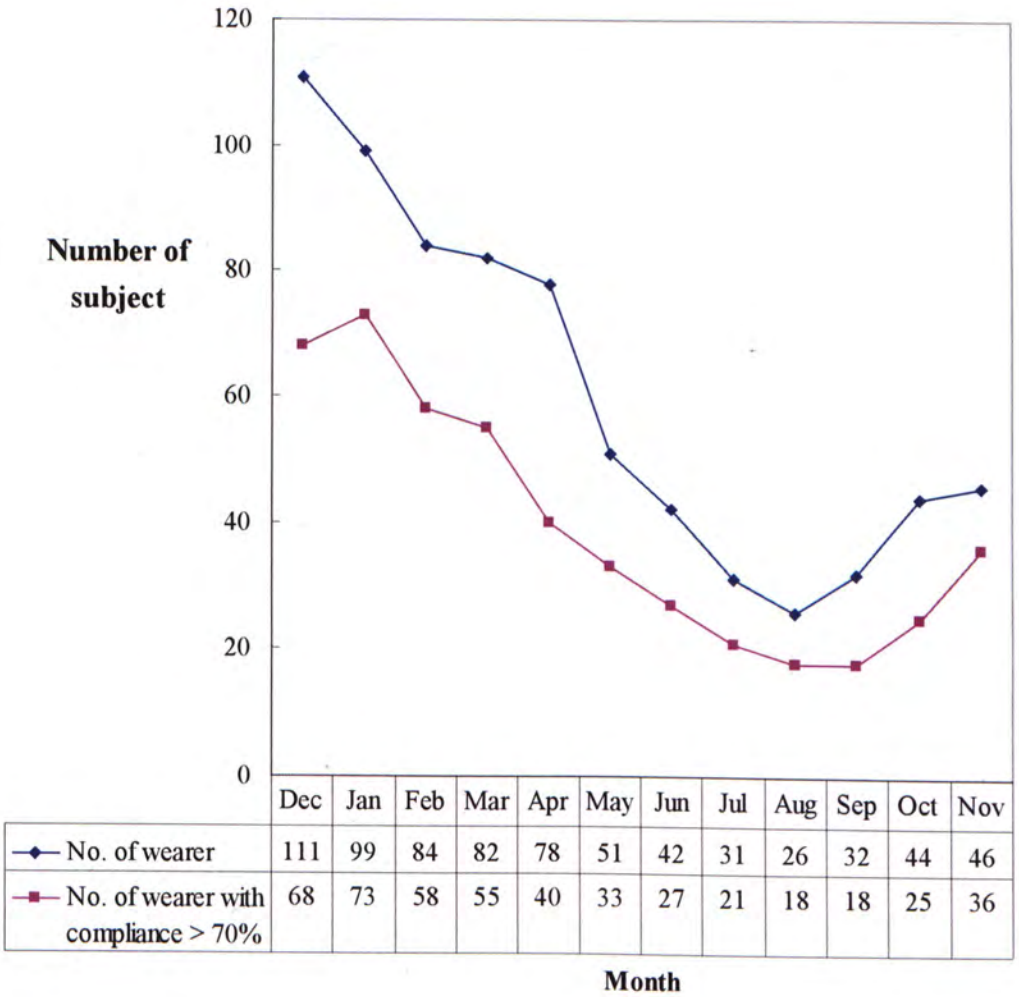
Figure 3.16 Force attenuation properties of the 12mm prototype in five consecutive impact under low impact condition



Month	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Avg
Day time	58.6	67.3	57.6	53.2	44.7	33.3	27.2	21.7	18.4	20.7	27.7	35.4	40.6
Night time	72.4	65.5	57.1	53.8	41.4	32.8	27.6	21.3	17.8	19.5	27.0	34.7	40.1
Whole day	65.9	66.5	57.2	53.6	43.0	33.0	27.7	21.5	18.1	20.2	27.2	35.1	40.4

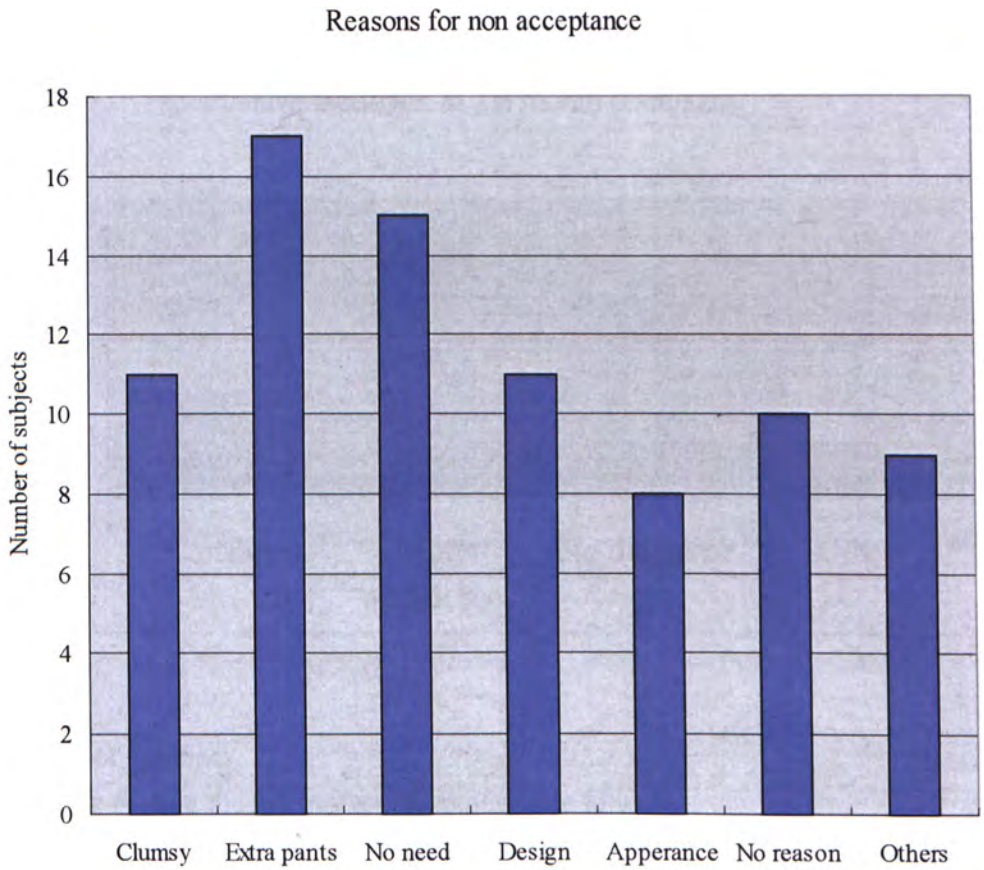
Difference in the trend of day and night time compliance: F score = 0.025, p=0.85
Difference in the compliance across study period: F score = 64.5, p<0.001

Figure 3.17 Compliance rate of the hip protector across the study period



	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
No. of wearer	111	99	84	82	78	51	42	31	26	32	44	46
No. of wearer with compliance > 70%	68	73	58	55	40	33	27	21	18	18	25	36

Figure 3.18 Number of subjects wearing hip protector across the study period



Specific reasons:

(1) Clumsy: clumsy in positioning the pads, the wearing and removing of the pants

(2) Extra pants: need to wear additional pants

(3) No need: not necessary as self perceived risk of fall or fractures was low

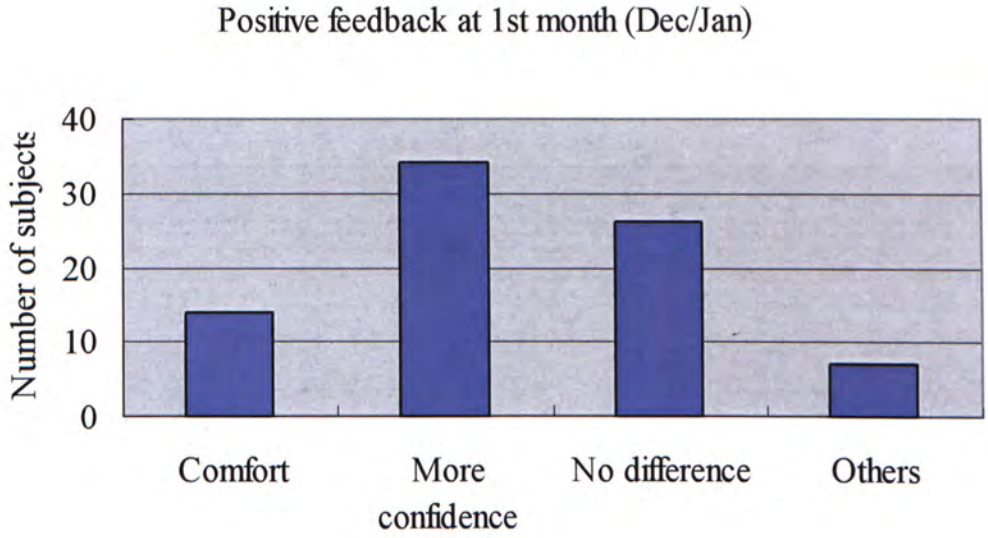
(4) Design: did not like the fabric materials or the design of the pants

(5) Appearance: did not like the appearance after wearing or bulkiness of the pads

(6) No reason: no specific reason was given for non acceptance

(7) Others: included concerning the laundry problems, discomfort, heat wave, forgetfulness etc.

Figure 3.19 Reason of non acceptance of hip protector by the subjects (N=61)



Definitions of feedback

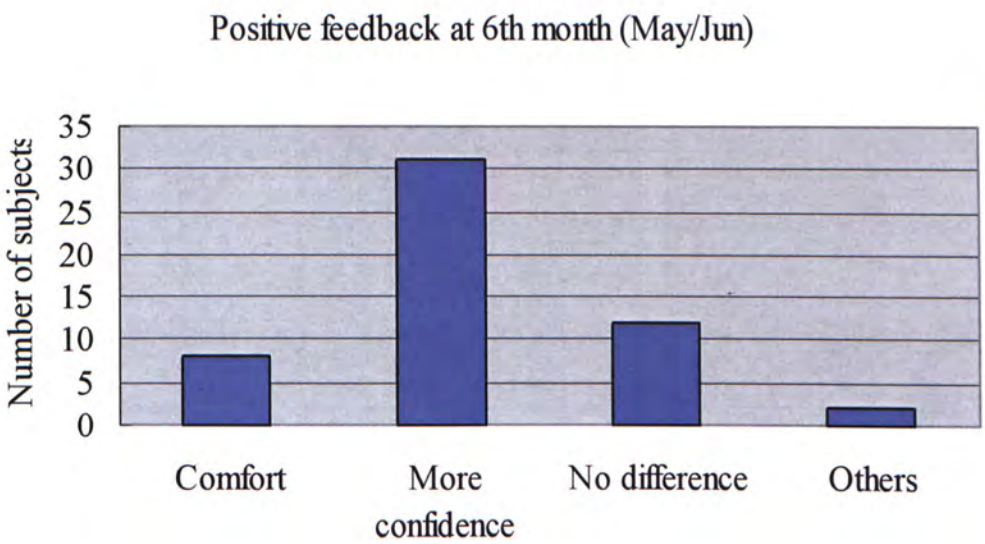
(1) Comfort: feeling the hip protectors comfortable to wear

(2) More confident: gaining of confidence against fall after wearing of hip protector

(3) No difference: regarding the hip protector as normal under garment

(4) Others: other positive feedback including getting warmer after wearing, pain relieving etc.

Figure 3.20 Positive feedback in using hip protector at the end of the first month (Dec/Jan) (N=118)



Definitions of feedback

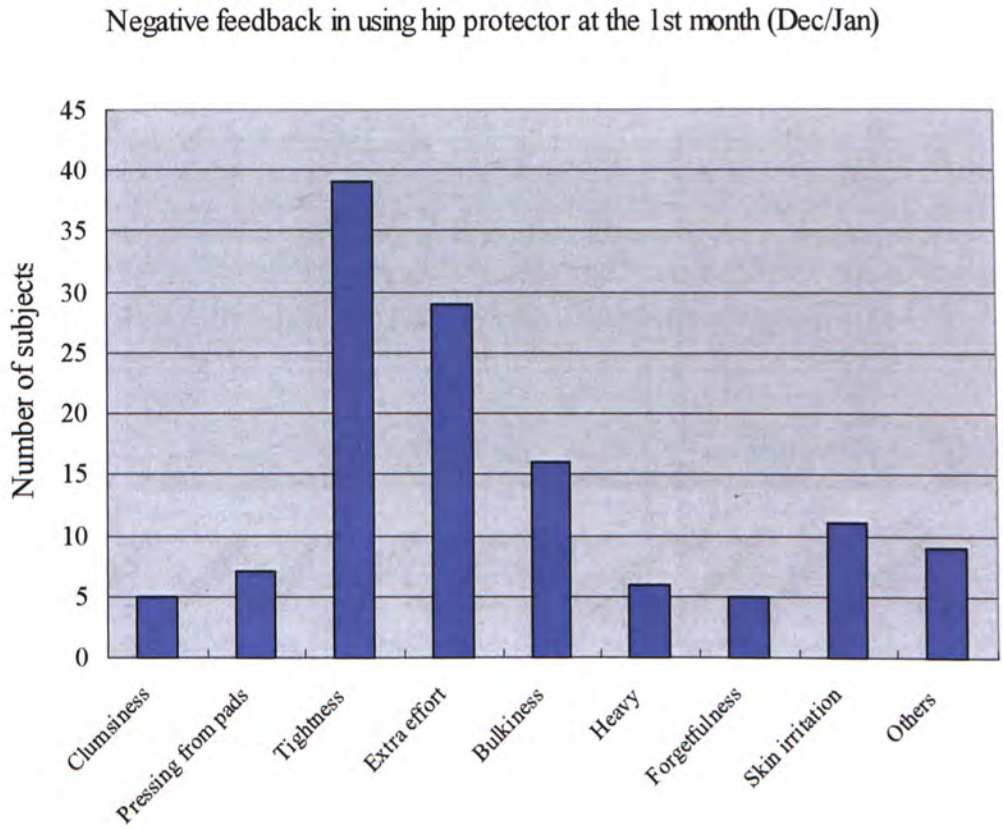
(1) Comfort: feeling the hip protectors were more comfortable to wear

(2) More confident: gaining of confidence against fall after wearing of hip protector

(3) No difference: regarding the hip protector as normal under garment

(4) Others: other positive feedback including getting warmer after wearing, pain relieving etc.

Figure 3.21 Positive feedback in using hip protector at the end of the first month (May/Jun) (N=97)



Definitions of feedback:

(1) Clumsiness: clumsy in positioning the pads, the wearing and removing of the pants

(2) Pressing from pads: discomfort caused by pressing from pads while dressing

(3) Tightness: discomfort caused by the tightness of the pants

(4) Extra effort: extra effort or time is needed for dressing and removing the pants, hinder activities of daily living like toileting or dressing

(5) Bulkiness: bulkiness of the hip protector adds further difficulties in dressing additional outer pants or trousers (especially when the weather was cold and subjects needed to dress additional trousers)

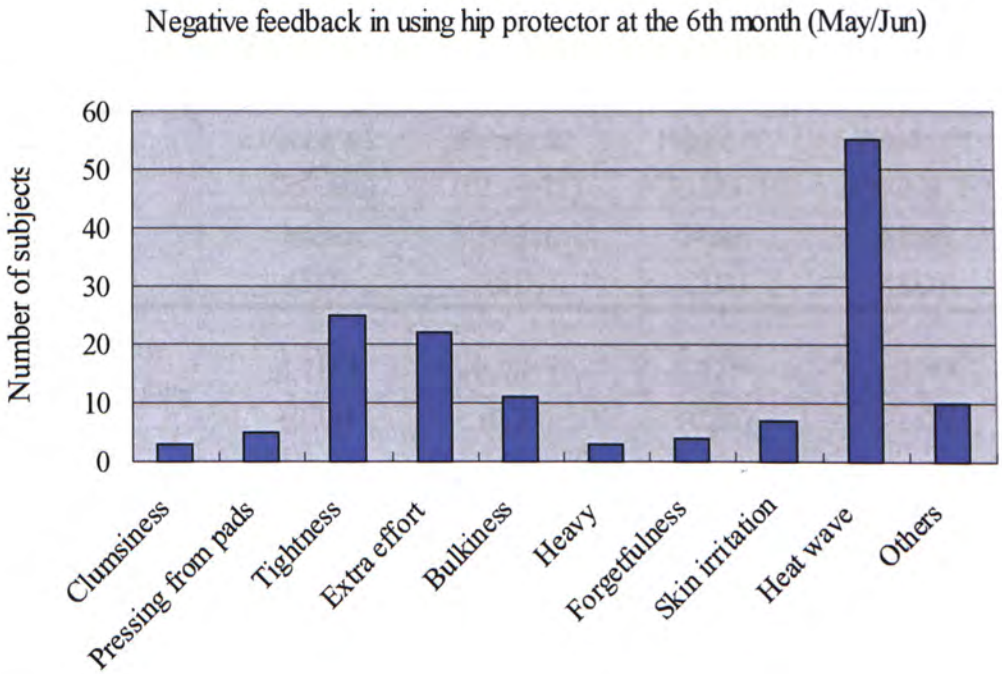
(6) Heavy: the hip protector was heavy and some subjects needed to pull up the pants regularly

(7) Forgetfulness: forget to wear hip protector

(8) Skin irritation: skin irritations like itchiness after wearing hip protector

(9) Other reasons includes too hot to wear, useless, and other non-specific reasons

Figure 3.22 Negative feedback in using hip protector at the end of the first month (Dec/Jan) (N=118)



Definitions of feedback:

(1) Clumsiness: clumsy in positioning the pads, the wearing and removing of the pants

(2) Pressing from pads: discomfort caused by pressing from pads while dressing

(3) Tightness: discomfort caused by the tightness of the pants

(4) Extra effort: extra effort or time is needed for dressing and removing the pants, hinder activities of daily living like toileting or dressing

(5) Bulkiness: bulkiness of the hip protector adds further difficulties in dressing additional outer pants or trousers (especially when the weather was cold and subjects needed to dress additional trousers)

(6) Heavy: the hip protector was heavy and some subjects needed to pull up the pants regularly

(7) Forgetfulness: forget to wear hip protector

(8) Skin irritation: skin irritations like itchiness after wearing hip protector

(9) Heat wave: too hot to wear hip protector

(10) Other reasons includes useless, physical difficulties, and other non-specific reasons

Figure 3.23 Negative feedback in using hip protector at the end of the sixth month (May/Jun) (N=97)

Table 3.1 Fabric test result

	Fabric #1 (Bo Lam)	Fabric #2 (CL-3011)	Fabric #3 (CL-2881H)	Fabric #4 (CL-2987H)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Air permeability ($cc/cm^2/s$ at 100Pa difference)	6.71** (0.33)	**8.78**** **(0.23)**	5.22** (0.15)	7.30** (0.17)
Moisture absorbency (s)	3.18* (0.52)	6.44** (1.06)	9.20** (1.46)	**1.26*** **(0.13)**
% of shrinkage after laundry (parallel to fibre width)	5.68 (0.33)	5.76 (0.22)	7.84** (0.36)	**1.52**** **(0.44)**
% of shrinkage after laundry (parallel to fibre length)	5.28** (0.33)	3.52 (0.18)	4.16 (0.61)	**0.56**** **(0.22)**

*Significantly different from all other fabrics at $p<0.05$

**Significantly different from all other fabrics at $p<0.01$

The value in bold was the one with the best performance in that particular test

Table 3.2 Summary of anthropometric measurements of different size group

All measurement in cm	Group XS	Group S	Group M	Group XL	Group L	Total
	N=19	N=20	N=17	N=7	N=5	N=68
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Waist circumference	76.0 (2.2)	83.0 (2.0)	89.5 (2.2)	104.6 (3.1)	97.4 (2.3)	85.9 (9.2)
Hip circumference	88.8 (4.5)	91.9 (4.9)	96.4 (7.0)	109.1 (6.7)	103.6 (9.8)	94.8 (8.6)
First round circumference	45.9 (3.9)	46.6 (4.6)	50.0 (5.8)	56.3 (5.8)	53.8 (4.5)	48.8 (5.8)
Vertical distance between waist and first round	28.2 (2.4)	28.2 (2.5)	28.2 (3.1)	29.0 (4.4)	27.0 (2.7)	28.1 (2.8)
Vertical distance between waist and hip	19.5 (3.4)	17.5 (3.5)	17.8 (3.0)	17.4 (5.4)	16.8 (1.3)	18.1 (3.5)
Vertical distance between waist and greater trochanter	16.5 (1.7)	16.2 (2.5)	16.7 (2.8)	16.1 (3.0)	15.4 (3.2)	16.3 (2.4)
Height	149.0 (5.6)	150.0 (5.6)	156.2 (8.4)	151.0 (7.9)	157.0 (11.1)	151.7 (7.6)

Table 3.3 Duration of impact of different prototype under the low and high impact condition (mean values from five samples)

Prototype	Impact	Impact time	
		Mean (ms)	Std. Deviation
No pad high impact		1.6	0.48
No pad low impact		1.6	0.48
2mm prototype	1st	16.4	1.14
(Low impact)	2nd	16.4	1.14
	3rd	16.6	0.55
	4th	18.2	1.92
	5th	16.0	1.41
2mm prototype	1st	17.2	2.95
(high impact)	2nd	17.2	2.59
	3rd	14.8	2.95
	4th	17.8	1.64
	5th	15.8	1.92
7mm prototype	1st	25.8	1.64
(Low impact)	2nd	26.2	1.92
	3rd	26.4	0.89
	4th	28.6	3.05
	5th	25.6	2.19
7mm prototype	1st	24.0	4.24
(High impact)	2nd	23.8	4.09
	3rd	20.2	4.60
	4th	25.0	2.45
	5th	21.8	3.03
12mm prototype	1st	38.4	2.51
(Low impact)	2nd	39.2	3.11
	3rd	39.2	1.30
	4th	42.8	4.97
	5th	38.4	3.29
12mm prototype	1st	36.0	6.36
(High impact)	2nd	35.8	6.42
	3rd	30.4	7.09
	4th	37.6	3.78
	5th	32.8	4.60

Table 3.4 Characteristics of the participating hostels

	Hostel K (N=40)	Hostel T (N=52)	Hostel F (N=68)	Hostel Y (N=19)
Location	Wong Tai Sin	Tseun Kwan O	Kwun Tong	Shatin
No. of subjects recruited	40	52	68	19
Discipline of contact person	Nurse	Nurse	Nurse	Occupational therapist
No. of responsible staff (including the contact person)	2	3	3	2
Staff to subject ratio (1:x)	20	17	23	9.5
No. of change of contact person during study period	1	0	0	0

Table 3.5 Demographics and fall history of subjects in different hostels

	Hostel K (N=40)	Hostel T (N=52)	Hostel F (N=68)	Hostel Y (N=19)	Overall (N=179)
Age[#]	82.85 (6.25)	81.75 (5.43)	81.69 (6.49)	84.53 (5.20)	82.27 (6.03)
Primary education or above	5 (12.5)^	13 (25.0)	22 (32.4)	8 (42.1)^	48 (26.8)
With fall history in previous year	3 (7.5)	13 (25.0)	10 (14.7)	2 (10.5)	28 (15.6)
With multiple fall history	0 (0)	4 (7.7)	2 (2.9)	1 (5.3)	7 (3.9)
With history of fracture since 50 years old	6 (15.0)	4 (7.7)	14 (20.6)	4 (21.1)	28 (15.6)
With history of hip fracture since 50 years old	2 (5.0)	0 (0)	7 (10.3)	2 (10.5)	11 (6.1)
With three or more co-morbidities	15 (37.5)	27 (51.9)	28 (41.2)	12 (63.2)	82 (45.8)

Values expressed as number (percentage) unless specified

[#]mean (std deviation)

^marginal significant difference among different hostels (p=0.055)

Table 3.6 Functional level of subjects in different hostels

	Hostel K (N=40)	Hostel T (N=52)	Hostel F (N=68)	Hostel Y (N=19)	Overall (N=179)
Modified Bathel Index	99.4 (2.0)	99.9 (0.7)	99.2 (2.5)	99.1 (3.9)	99.4 (2.2)
Power grip of dominant hand (kg)	14.9 (3.6)	17.6** (5.1)	15.1 (4.4)	13.1** (4.3)	15.6 (4.6)
Lateral pinch of dominant hand (kg)	5.1 (1.1)	5.0 (1.1)	5.0 (1.8)	4.6 (1.2)	5.0 (1.4)
Nine Hole Peg test (s)	21.4 (4.1)	21.8 (5.5)	21.4 (7.0)	21.5 (5.1).	21.5 (5.9)
With urinary incontinence[#]	11 (27.5)	12 (23.1)	28 (41.8)	6 (31.6)	57 (32.0)
Mini-Mental State Examination	20.3** (4.5)	23.4 (4.0)	23.2 (3.8)	24.1 (3.3)	22.7 (4.1)
Time up and go test (s)	14.4 (4.6)	14.3 (5.0)	17.5 (11.5)	16.9 (8.1)	15.8 (8.4)
Need of walking aids[#]	12 (30.0)	14 (26.9)	20 (29.4)	10 (52.6)	56 (31.3)
Activity-specific Balance Confidence scale	102.1 (25.1)	114.0 (28.1)	82.8** (36.4)	109.6 (28.7)	99.8 (33.7)

Values expressed as mean (std deviation) unless specified

[#]number (percentage)

**significant difference among different hostels at $p<0.01$ level

Table 3.7 Acceptance rate of hip protector among different hostels

	Hostel K (N=40)	Hostel T (N=52)	Hostel F (N=68)	Hostel Y (N=19)	Average (N=179)
Non-acceptance group	19 (47.5%)	22 (42.3%)	18 (26.5%)	2 (10.5%)	61 (34.1%)
Acceptance group	21 (52.5%)	30 (57.7%)	50 (73.5%)	17 (89.5%)	118 (65.9%)

Pearson Chi-Square: 11.22

$P<0.05$

Table 3.8 Mean compliance rate of hip protector across different hostels

	Hostel K	Hostel T	Hostel F	Hostel Y	Overall
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Day time	27.6 (34.9)	41.8 (34.7)	42.3 (33.4)	49.0 (32.1)	40.6 (34.2)
Night time	28.0 (35.0)	41.6 (34.6)	42.2 (33.9)	46.3 (34.2)	40.1 (34.4)
Whole day	27.8 (34.9)	41.8 (34.6)	42.3 (33.6)	47.5 (33.2)	40.4 (34.1)

All values are in percentage

Difference in compliance rate across hostels:

P values: 0.294 (Whole day), 0.234 (Day time), 0.335 (Night time)

Table 3.9 Incidence rate of falls and related injuries among the subjects

	Unprotected fall*		Protected fall**
	Non-acceptance group (n=61) No. of events (Incidence rate)***	Acceptance group (n=118) No. of events (Incidence rate)***	Acceptance group (n=118) No. of events (Incidence rate)***
No significant injuries	4 (6.58)	3 (4.27)	4 (8.39)
Soft tissue injury	2 (3.28)	6 (8.53)	4 (8.39)
Head injury	1 (1.64)	2 (2.84)	1 (2.10)
Fractures (other than hip fractures)	3 (4.92)	1 (1.42)	1 (2.10)
Hip fractures	1 (1.64)	1 (1.42)	0 (0)
Total	11 (18.06)	13 (18.48)	10 (20.98)

*Protected fall: falls occurred while hip protector was being worn

**Unprotected fall: falls occurred while hip protector was not being worn

***Incidence rate was calculated as

$$\frac{\text{Number of events}}{\text{(Number of subjects X average non-compliance or compliance rate)}}$$

For the non-acceptance group, the non-compliance rate was 100%;

For the acceptance group, the non-compliance rate was 59.6% while compliance rate was 40.4%

The values are expressed as per 100 person year.

Table 3.10 Comparison of demographics and fall history from subjects who accepted to wear hip protector and those who did not

	Acceptance (n=118)	Non Acceptance (n=61)	P value
Age	82.2 (6.1)#	82.4 (5.9)#	0.88
With primary or above education	35 (29.7)	13 (21.3)	0.23
Fall at least once in previous year	19 (16.1)	9 (14.8)	0.81
Fall at least twice in previous year	6 (5.1)	1 (1.6)	0.25
With history of fracture since the age of 50	21 (17.8)	7 (11.5)	0.27
With history of hip fracture since the age of 50	6 (5.1)	5 (8.2)	0.30
With three or more comobidities	60 (50.8)	22 (36.1)	0.06^

All values express in number (percentage) unless specified
#mean (std deviation)
^marginal significance

Table 3. 11 Comparison of functional levels from subjects who accepted to wear hip protector and those who did not

	Acceptance (n=118)	Non Acceptance (n=61)	P value
Modified Bathel Index	99.7 (1.4)	98.9 (3.3)	0.07
Power grip of dominant hand (kg)	15.8 (4.8)	15.2 (4.2)	0.42
Lateral pinch of dominant hand (kg)	5.1 (1.5)	4.8 (1.1)	0.15
Nine Hole Peg test (s)	21.4 (6.2)	21.8 (5.2)	0.73
With urinary incontinence	35 (29.9)#	22 (36.1)#	0.40
Mini-Mental State Examination	22.9 (4.0)	22.4 (4.5)	0.45
Time up and go test (s)	15.4 (6.9)	16.5 (10.6)	0.46
Need of walking aids	40 (33.9)#	16 (26.2)#	0.29
Activity-specific Balance Confidence scale	97.8 (32.7)	104.6 (35.9)	0.30

All values express in mean (std deviation) unless specified
#number (percentage)

Table 3.12 Associations between compliance and non-compliance and subject's feedback in using hip protector

	Correlation Coefficient	P-value
#Experience the hip protector as comfort	0.479	<0.001
#Gaining of confidence against fall after wearing hip protector	0.275	0.003
Regard the hip protector as normal under garment	0.109	0.24
Clumsy in positioning the pads, the wearing and removing of the pants	-0.137	0.15
Discomfort caused by pressing from pads while dressing	-0.171	0.067
^Discomfort caused by the tightness of the pants	-0.400	<0.001
Extra effort or time is needed for dressing and removing the pants, hinder activities of daily living like toileting or dressing	-0.084	0.371
Bulkiness of the hip protector adds further difficulties in dressing additional outer pants or trousers	-0.104	0.26
^Hip protector was heavy and needed to pull up the pants regularly	-0.147	0.12
Skin irritations like itchiness after wearing hip protector	-0.146	0.119
^Too hot to wear hip protector*	-0.261	0.022

*Only subjects still wearing hip protector after the fifth month was included in calculation

#Significant associations with compliance

^Significant associations with non-compliance

Table 3.13 Association of characteristics and functional levels of subjects with compliance

	Pearson's Coefficient (r)/ Correlation Coefficient	P value
#Age	0.015	0.88
*With primary or above education	0.09	0.33
*Fall at least once in previous year	-0.031	0.74
*Fall at least twice in previous year	0.164	0.079
*With history of fracture since the age of 50	0.129	0.172
*With history of hip fracture since the age of 50	0.121	0.19
#No. of co-morbidities	-0.023	0.81
#Modified Bathel Index	0.167	0.071
#Power grip of dominant hand (kg)	0.095	0.31
#Lateral pinch of dominant hand (kg)	-0.104	0.26
#Nine Hole Peg test (s)	0.122	0.153
*With urinary incontinence	-0.006	0.94
#Mini-Mental State Examination	0.058	0.53
#Time up and go test (s)	-0.024	0.80
*Need of walking aids	0.032	0.73
#Activity-specific Balance Confidence scale	0.118	0.26

#Pearson's correlation test

*Spearman's correlation test

Table 3.14 Score of the Activities Specific Balance Scale for the subjects before and after the wearing of hip protector

N=61	Before wearing HP		After wearing HP for 3 months		P
	Mean	SD	Mean	SD	
Walking around the house	8.13	1.66	8.62	1.582	<0.001
Walking up and down stairs	6.77	2.10	6.81	2.039	0.66
Picking up slipper / something from the floor	7.23	2.10	7.17	1.880	0.60
Reaching at your eye level	7.53	2.17	7.62	1.883	0.57
Reaching while on your tiptoes	6.36	2.55	6.43	2.393	0.50
Reaching while standing on a chair	4.98	2.58	5.06	2.488	0.42
Sweeping the floor	7.00	2.61	7.09	2.244	0.47
Walking outside to a nearby bus stop	7.15	2.15	7.36	1.905	0.09
Getting in / out of a bus	6.02	2.38	6.30	2.206	0.04
Walking across a parking lot	6.91	2.29	7.02	1.939	0.40
Walking up and down a ramp	6.26	2.35	6.30	2.302	0.64
Walking in a crowded mall	6.36	2.14	6.45	1.987	0.32
Being bumped while walking in a crowd	4.47	2.46	4.60	2.420	0.28
Using an escalator while holding the railing	6.79	2.69	6.87	2.455	0.49
Using an escalator without holding the railing	4.47	2.97	4.62	2.931	0.16
Walking on slippery floors	5.30	2.65	5.28	2.585	0.84
Total Score	101.93	31.10	103.72	29.340	0.01

Note: higher score indicates better rating in confidence against fall

Discussion

IV. DISCUSSION

Hip protectors can be an effective strategy in prevention of hip fractures among elderly (Parker et al. 2005, Sawka et al. 2005, Parker et al. 2006). There are three factors affecting the effectiveness of a hip protector in prevention of hip fractures: its force attenuating properties, the compliance of subjects in wearing hip protector and whether the subjects wear the hip protector properly. Force attenuation property of a hip protector is crucial in determining its ability in protection of the hip from fracture while compliance and proper wearing are also important in determining its clinical efficacy. However, in most of the studies, poor acceptance and compliance remain the problems of hip protector (van Schoor et al. 2002, Parker et al. 2005, Sawka et al. 2005). Investigating determinants of compliance and non-compliance, like factors related to the design of the hip protector (Villar et al. 1998, Birks et al. 1999, Cameron et al. 2001, Hubacher and Wettstein 2001, Cryer et al. 2002, Patel et al. 2003, Forsén et al. 2004a, O'Halloran et al. 2005) and factors related to the characteristics of users (van Schoor et al. 2003b, Kurlle et al. 2004a, Warnke et al. 2004), are crucial in identifying strategies in facilitating the use of hip protectors (Parkkari et al. 1998, Hubacher and Wettstein 2001, Cameron et al. 2003, Meyer et al. 2003, O'Halloran et al. 2004).

In the current study, a modified hip protector for Chinese elderly was developed. The current design was proven to be effective in attenuating the impact force to a safety level in the occurrence of fall. The determinants of compliance and non-compliance of this hip protector among Chinese elderly were also successfully investigated.

4.1 Development of a hip protector for Chinese elderly

A modified hip protector for Chinese old ladies was successfully developed in this study. This was the first study that taking the local anthropometric data, fabric analysis as well as the properties of the energy shunting and cushioning materials into account for the design of appropriate pants and pads of the hip protector for Chinese old ladies to use in Hong Kong. There were several modifications including both the design of pants and pads of the hip protector made which may facilitate its use in Hong Kong.

4.1.1 Successful modifications made to the pads

4.1.1.1 More comfort to wear with silicon cushioning materials added

The pad developed was a combination of energy shunting and energy absorption pads. The previous types of pads can be categorized in two groups according to their force attenuation principles: the energy absorption types and the energy shunting types (O'Halloran et al. 2005b). The types of pads were shown to have association with compliance and the softer energy absorption pads seems to be associated with better compliance in previous studies (Suzuki et al. 1999, Yoshimura et al. 1999, O'Halloren et al. 2005), though further investigations is needed. Another factor, which is the most important one for hip protector, needed to be considered is the force attenuation properties of the pads. It is known that softer energy absorption pads have only about half the force attenuation power than the harder energy shunting type hip protector (Robinovitch et al. 1995, Kannus et al. 1999). In order to make the energy absorption pads more effective in force attenuation, padding materials with at least 10cm in thickness was suggested to be used (Parkkari et al. 1994), which made the

pads more bulky and might have negative effect on acceptance and compliance. On the other hand, the major problem of the energy shunting pads is poor compliance as a result of the pressing of the hard pads while wearing, which may make the users feel uncomfortable. It is not uncommon to see that studies using energy shunting pads usually have unsatisfactory compliance ranging from 19% to 57% (Cameron et al. 2001, Cryer et al. 2002, Forsen et al. 2003, O'Halloran et al. 2004). Therefore the major problems of the previous designs were the poor compliance of the energy shunting type, though they generally had good force attenuation properties, while energy absorption type may have better compliance but the force attenuation properties seems to be inadequate, which was reported to attenuate only about 50% of the impact force and the remaining amount was similar to the fracture threshold of the proximal femur (Kannus et al. 1999).

The modified pad was shown to be successful as shown by its less negative feedback from the users in the present study. Only 6% of the user reported uncomfortable after wearing hip protector which was related to the pads. Comparing with Villar's trial on female residents of old age homes using an energy shunting type hip protector (the SafeHip), which is one of the commonest hip protector used in many studies, 37% of the subjects reported similar feedback in using the hip protector (Villar et al. 1998). The major reason for such decrease in this negative feedback might be due to the addition of a 7mm thickness silicon cushioning layer which decreased the pressing from the pads while wearing the hip protector.

4.1.1.2 Better mechanical properties with semi-flexible plastic and silicon pad

The materials of the previous energy shunting pads were usually made of hard

plastic or semi-flexible plastic (Parkkari et al. 1995, Weiner et al. 2002). It was believed semi-flexible plastic were in advantage to hard non-flexible plastics as they usually had better recover ability after compression and energy absorbing capacity, which were essential characteristics for making the pads (Parkkari et al. 1994). It is hypothesized that during the impact, semi-flexible hard plastic will attenuate the impact force besides by shunting away part of the energy by the hard pads, and also with certain degree of shape change by compressing under impact. It is believed this will additionally absorb some of the impact energy. Besides its well-known cushioning effect for reducing discomfort, another reason for choosing silicon is it has good energy absorption properties. Silicon was proven to have nearly 50% better energy absorption capacity than plastozole and foams, which are commonly used for cushioning materials in other models of hip protectors (Okuizumi et al. 1998). Thus, silicon might add additional advantage to the force attenuation properties of the pads. These properties were actually reflected in the mechanical test that nearly 93% of the impact force in a simulated fall condition was attenuated by our pad. When comparing with other similar studies which demonstrated their hip protectors usually made of hard plastics and plastozole could attenuate 46%-95% of impact force (Kannus et al. 1999, Weiner et al. 2002), our model was superior to most of other models in this aspect. Comparing with two of the commonest model of hip protector, our model was comparable with KPH (Finland), which can attenuate nearly 90% of impact force, but was much more effective than Safehip® (Denmark), who could only attenuate around 60% of impact force under similar impact conditions (Kannus et al. 1999).

4.1.1.3 Smaller in dimension of the present model might improve appearance after wearing

The dimensions of the pads might affect the hip protector compliance. Previous studies showed that hip protectors with smaller size might have positive effect on compliance since it would not be seen by others while wearing as those of the more bulky designs (Myers et al. 1995, Butler et al. 1998, Patel et al. 2003). Therefore, the size of the hip protectors should be as small as possible while maintaining effective force attenuation properties as well as covering the trochanter well. So finally there were several modifications made to the dimensions of our pads. Parkkari and coworkers identified in their in vivo biomechanical study that there should be at least 1.5 cm gap between the inner surface of the pads and the skin around the greater trochanter, which is considered to be safe to avoid direct transmission of the impact force to the greater trochanter in a fall situation (Pakkari et al. 1995). In our model, the inner surface of the pad was also 1.5 cm above the skin, and this was considered to be safe. The thickness of the pad was also comparable to the existing hip protector developed by others who also used 3mm thickness hard plastic shield (Okuizumi et al. 1998, Wiener et al. 2002). The sizes of current known types of hip protectors with mechanical studies done range from 8.5 cm to11.5 cm in the maximum width, 13.5 cm to 19 cm in the maximum length, and 2.5 cm to 4.5 cm in the maximum height (Mills 1996, Kannus et al. 1999, Weiner et al. 2002). The dimensions of our pads were 9x14x2.5cm (maximum width x length x height). Compares to two of the most commonest hip protector, the size of our model was found to be smaller than both the Safehip®, whose dimensions were 11 x 15.4 x 2.5 cm, and the KPH, whose dimensions were 8.5 x 19 x 3.5 cm. The advantage of making the pads smaller was seen by fewer subjects claimed the hip protector was bulky to wear as compared with

other similar study. In the present study, there were 14% of the subjects complained about the hip protector was bulky which might affect their appearance and activities of daily living. However, it was seen that a similar overseas study on elderly hostel residents with the application of Safehip® hip protector, more than a quarter of the subjects stopped wearing the hip protector because of the same compliant about the hip protector (Patel et al. 2003).

4.1.2 No significant improvement on compliance with modification of the pants

Good design and well-fitted pants are crucial determinants for better compliance (van Schoor et al. 2002). However, there were no previous study talking about the design of the pants, particularly the anthropometric concern and the fabric materials. There was one study talked about the anthropometric concern in development of the hip protector, however, the investigators applied the data for development of the pads only (Parkkari et al. 1995). Several modifications were made to the pants including collection of anthropometric data for developing a size chart for making different sizes of the pants and selection of the most suitable fabric materials for making the pants, however, these modifications did not improve the compliance.

Since the most important function of the pants was to keep the pads in place, the pants should be tight fit to the users. Although anthropometric data were collected for making the pants as fit as possible, there were still 38% of subjects claimed the fitting problem of the hip protector was either being too tight (35%) or too loose (3%), which made them uncomfortable to wear. This was also one of the major determining factors for non-compliance. Other studies also found this problem with their pants (Butler et al. 1998, Suzuki et al. 1999, Hubacher and Wettstein 2001). Butler and coworkers

found that tightness of hip protector was the major concern for subjects in using it (Butler et al. 1998), while in Hubacher's study, the problem of fitting was also found to be a significant discriminator between wearers and non wearer (Hubacher and Wettstein 2001). Suzuki also added the reason for tightness that subjects were using more underwear in winter (Suzuki et al. 1999). Most of our subjects did not like to wear the hip protectors directly as the underwear, they used to wear their own underwear beneath the hip protector. This might make them feel additional tightness. The situation was more serious in winter where subjects needed to wear extra underwear to keep warm. This also explained the reason that more subjects complained the pants were too tight in winter (35%) than in summer (23%). Therefore development of tailor-made pants might be helpful in reducing individual fitting problems and hence the compliance rate. An alternative way to solve the problem related to fitting is to explore "non-pant" designs of hip protector.

Functional tests were done to help us to select the best fabric material for making the pants. The fabric materials were good at withstanding shrinkage after repeated laundry in functional test. There was also no compliant about this problem of the pants throughout the study. However, although the fabric was the best in air permeability and moisture absorbency, it was found that 50% of the subjects found that it was too hot to wear the pants especially in summer. The major reason for this is that most of the subjects wear the pants as an additional one rather than replacing their normal underwear, this made them hot as they were wearing two undergarments.

4.2 Sufficient mechanical properties of hip protector demonstrated

The current hip protector was proven to be effective in attenuating the impact

force in the occasion of fall to a safety level right below the fracture threshold of the proximal femur. The result was similar to that of others that hip protector with energy shunting component could attenuate up to 90% of impact forces (Mills 1996, Kannus et al. 1999, Weiner et al. 2002).

4.2.1 Mechanical test set up

In the current mechanical test set up, a fall simulation condition was created by a drop weight test system. Force attenuation properties of the pads can be tested in fall simulation tests (Mills 1996, Okuizumi et al. 1998, Kannus et al. 1999, Weiner et al. 2002) and also the addition of real fall test (Weiner et al. 2002). In fall simulation tests, usually there is a weight released from certain height (Mills 1996, Okuizumi et al. 1998, Weiner et al. 2002) or as a pendulum released from certain angle to create the impact as that in a fall situation (Kannus et al. 1999). However, it is found that there are great variations among different studies in the testing system. Firstly, most of the studies used energy absorption materials like polyethylene foam to simulate soft tissues over the hip of elderly person in the mechanical tests, however, the thickness of the foams varied from 5 to 20mm (Parkkari et al. 1995, Weiner et al. 2002). Secondly, there were some studies using springs in the testing systems to simulate the force attenuation by the pelvic system (Parkkari et al. 1995, Kannus et al. 1999) but others did not (Mills 1996, Okuizumi et al. 1998, Weiner et al. 2002). The soft tissues and the pelvis system may absorb certain amount of energy during a fall-induced impact to the hip. However, the amount of the energy that these protective systems could absorb remains unclear. Therefore it is difficult to simulate a perfect falling condition based on current knowledge. On the other hand, Weiner and co-workers conducted the first quantitative study on force attenuation properties in real falling

conditions (Weiner et al. 2002). However, only young volunteers were recruited to perform the fall test in this study. It may not be possible to recruit elderly person to perform these fall tests.

In our current testing system, it was designed to remove all the protective systems including the springs and foams which simulate the pelvic system and soft tissues covering the hip respectively. Since there was great variation of the force attenuating properties of the soft tissue and the pelvic system across individuals and the mechanisms are not easy to simulate perfectly, a risk of overestimation of the force attenuation properties of the simulated systems may encountered, which will in turn overestimate the force attenuation properties of the pads (Mills 1996). Therefore a more conservative approach was used by removing all these components. Since the force attenuation by the soft tissue and the pelvic system was not taking into account, which might attenuate up to 15% of the impact force (Kannus et al. 1999), the amount of impact force received by the proximal femur after the attenuation by the hip protector would be somewhat below to what this experiment indicated.

Unlike other studies, the current study used a force plate rather than a single load cell to record the amount of force in the drop weight test. In the experimental set up created by Mills, a single load cell was used to simulate the greater trochanter, which were embedded in flesh simulating the muscles and soft tissues (Mills 1996). There may be two problems encountered. Firstly the load cell may not simulate perfectly to the shape and size of the greater trochanter, the impact record in the testing situation may not be the force that the greater trochanter actually received. Secondly, the impact measurements were relied solely on the single load cell, the positioning of the

simulated anatomical systems and the weight should be in very high accuracy so that measurement of different impacts was under the same condition. In the current set up, a force plate with four load cells located in each corner of the rectangular platform was used to record the amount of impact directly acting on the platform. The force recorded by each of the four load cells were then combined together to calculate the total amount of force that the dropping weight produced. It was also found that under comparable dropping height with other similar studies, a much lighter weight was needed to provide similar amount of impact (Mills 1996, Okuizumi et al. 1998). It was because in other experiments, only part of impact was recorded by the single load cell, some impacts were actually diverted by the simulated anatomical systems. But in the current testing system, all the impacts acting on the platform were recorded by the four load cells. The amount of force recorded was simply used to compare directly with that of the fracture threshold of the femur.

4.2.2 Mechanism of force attenuation

Hip protector with energy shunting component was found to be with good force attenuation properties (Kannus et al. 1999, Weiner et al. 2002). In Weiner's study, an energy shunting hip protector was found to effectively attenuate 95% of impact force (Weiner et al. 2002) while Kannus and co-workers demonstrate that their hip protector would attenuate up to 90% of impact force (Kannus et al. 1999). Similar to these findings, the modified hip protector used in this study also demonstrated good force attenuation properties. It was shown that it attenuated 93.5% of impact force under low impact condition and 93.2% under high impact condition. It was also found that under all the impact conditions, the hip protector attenuated the forces to levels that were significantly below the fracture threshold of the proximal femur. If the

protection of the soft tissue and the pelvic system were taken into account, the actual force acting on the greater trochanter might be less than the amount that the current result indicated. There was also no significant difference in the force attenuation properties of the same pads across successive impacts, and all these values were significantly below the fracture threshold of the proximal femur. This property is important for providing adequate protection to the user with the same hip protector even when the users fall repeatedly.

From the result of the weight dropping test, the mechanism of force attenuation of this hip protector was shown by increasing the impact time. It was found that the impact time with the application of the pads was significantly longer than that of the impact without the pads. The time of impact increased from about 2ms to 25ms after the application of the pads. Since the impact time is inversely proportional to the force of impact, the increased duration of impact accounts for the lowering of the impact force. It was also shown that the impact time increased with increasing the thickness of the silicon pads, thus thicker pads were better in force attenuation. Therefore, it was believed that the silicon pads might contribute partly in attenuating the impact force. However, comparing with the result by Okuizumi, silicon alone was able to provide marginal force attenuation only (Okuizumi et al. 1998). It was therefore believed that certain portion of the force attenuation was provided by the plastic shield. Although the amount of the portion was not shown in this study, it was demonstrated in other study that the application of a plastic shield would contribute to at least 60% of the total amount of force being attenuated (Okuizumi et al. 1998). The mechanism of force attenuation by the plastic shield is to divert the force away from the greater trochanter (Kannus et al. 1999). Apart from energy shunting, energy

absorption by the semi-flexible plastic may also occur. Little change on the force attenuation properties of the pads in successive impacts suggested the semi-flexible Orfit® shell operated pretty much within its elasticity limit.

4.3 No significant improvement on compliance shown

The average compliance of subjects in wearing the hip protector across the 12 months study period was 40.4%, which was comparable to other studies reported in literature (mean compliance rate: 44.4%) (Table 1.1). The average compliance rate in the first two months was about 66%, which is comparable to a previously reported local study with mean compliance of 65% for the first month of the study (Woo et al. 2003) and better than some of the foreign studies with mean compliance range from 37% to 60% in the first month of the trials (van Schoor et al. 2003, Forsen et al. 2004a, O'Halloran et al. 2004). When compared with the compliance at the beginning of the study, there was about 30% to 50% drop in compliance rate at the end of study (Hubacher et al. 2001, Cryer et al. 2002, van Schoor et al. 2003a, Forsen et al. 2004a, O'Halloran et al. 2004). Similar to these studies, the compliance as well as the number of subjects still wearing hip protector decreased as the study proceeded. There was 47% drop in the compliance and 58% of subjects discontinued to wear hip protector at the end of the trial.

It was observed that the compliance in other studies usually dropped as the studies began and was the poorest at the end of the studies. However, in our study, the compliance rate dropped to the lowest (18.1%) at the ninth month of the study (at summer time) and increased slightly in the last three months. There was seasonal change associated with the compliance rate. In Hong Kong, although summer usually

starts from June, but it has become very hot as early as April. From the record of the Hong Kong Observatory, the average day temperature in April 2005 was 25.4°C, and increased up to 32°C in July and maintained beyond 30°C in the following two months. The temperature gradually dropped starting from October. It was observed that the compliance rate of the hip protector was inversely associated with the temperature. In the hottest season (June – September), the compliance rate was the lowest, but when the temperature dropped in the later months of the study, the compliance rate increased. In fact, from the feedback of the subjects, feeling too hot to wear hip protector was the most significant determinant of non-compliance. The fact that all the hostels were not air-conditioned gave additional impact to the compliance especially in summer. However, in most of the other studies (Hubacher and Wettstein 2001, Cryer et al. 2002, van Schoor et al. 2003a, Forsen et al. 2004a, O'Halloran et al. 2004) which were conducted in Northern Europe, heat wave might not be a significant barrier of hip protector use as that was encountered in Hong Kong. This problem may not be easily solved especially in settings without air conditioning. One of the possible solutions to the problem may involve exploring designs of hip protector without using pants for holding the pads. This also can be one of the future directions in improving the current design and application of hip protector.

In the present study, the recording of compliance was done by the hostel staff. There were several methods of recording compliance as reported in the literature, which included self report or by caregiver in a dairy book (Parkkari et al. 1998, Kannus et al. 2000), daily record by hostel staff (Meyer et al. 2003, Woo et al. 2003) and unannounced check by hostel staff or project staff at random schedule (van Schoor et al. 2003a, Forsen et al. 2003, O'Halloran et al. 2004). Among these methods,

announced checking at random schedule was the most preferable one since it might truly reflect the real situation of the subjects in wearing hip protector (van Schoor et al. 2002). For studies done in residential facilities, checking the compliance of the residents by the hostel staff was considered to be an accurate method (Kurrle et al. 2004b). In the present study, the frequency of checking was fixed at eight times per month. However, in other study with similar checking method, they only checked the subjects three times across the 12-month study period (van Schoor et al. 2003a). The draw back for such low checking frequency is it may loss some important information such as monthly changes of compliance among the subjects.

4.4 Compliance at night time better than other studies

It was observed in this study that the day time and night time compliance was similar across the study period, which was in contrast with other studies that night time compliance was generally 30% to 90% poorer than that of the day time (Cryer et al. 2002, van Schoor et al. 2003a, Woo et al. 2003). The mean night time compliance of our study was 40% across the 12-month study period while others range from 3% to 30% (Cameron et al. 2001, Cryer et al. 2002, van Schoor et al. 2003a, Forsen et al. 2004a). In our study, the hip protector used was modified with a layer of silicon cushion added, which might reduce the pressing of the pads especially at night time where the hip protector was press against the bed when the subject is in side-lying. This may improve the comfort of the hip protector to be worn at bed. This might also be the reason that the compliance at night time was higher when compared with other studies.

4.5 Determinants of compliance mostly related to subjects' feedback of using hip protector rather than on their characteristics

It was found that the major determinants of compliance were associated with the feedback of the users. The feedback of the hip protector as comfortable to wear and gaining confidence against fall during daily activities after wearing the hip protector were significant determinants of compliance. Subjects who regarded the hip protector as normal undergarment were tended to be with higher compliance in using it. On the other hand, subjects experiencing the hip protector as too hot to wear and as too tight were significant determinants of non-compliance. These findings were congruent with that in literature that regarding the hip protector as comfortable to wear were the major determinant of compliance (van Schoor et al. 2002).

For the characteristics of the subjects, however, the present study showed that none of them associated significantly with the compliance of the subjects in using hip protector. Only the factor of repetitive history of fall seems to have positive association with compliance. The findings of this study were somewhat different to that of the other studies in this aspect. Warnke and co-workers studied a wide variety of subject's characteristics including demographics, fall and medical history as well as the functional status in the association with hip protector compliance (Warnke et al. 2004). They found that there was positive trend in association of hip protector compliance with history of fall and fracture. In other studies, there were some other characteristics of subjects were found to be associated with compliance and non-compliance to some extent. Factors including greater degree of dependence, cognitive impairment, urinary incontinence and fear of falling (van Schoor et al. 2003b, Warnke et al. 2004, O'Halloran et al. 2005a) might associate with compliance

while those including use of walking aids, lower self-rated health and perceived higher number of perceived barriers to hip protector use might associate with non-compliance (Kurrle et al. 2004a, Warnke et al. 2004). The reason for the discrepancy might be due to there were some other stronger determinants of hip protector compliance like the climate factor and the comfort to wear that the effect of weaker determinants like the history of fall and fracture on compliance might be masked. In fact, Warnke and co-workers also warn that most of the predictors related to characteristic of the users were not strong and some might be questionable in the prediction of compliance and non-compliance (Warnke et al. 2004). Hubacher and co-workers also suggested that other the factors associated with the subjects' characteristic, other possibly more important factors related to the design of hip protector and other factors related to characteristics of the hostel might also affect the compliance (Hubacher et al. 2001).

4.6 Better compliance observed in hostel with higher staff-to-subject ration and with occupational therapist as contact person

Inter-hostel effect on hip protector compliance was reported in other studies (Forsen et al. 2004a, Warnke et al. 2004, O'Halloran et al. 2005a). Factors including fewer changes of senior manager during the study period, greater proportion of residents with a higher degree of dependency, as well as higher staff to resident ratio were associated with higher compliance. Hubacher and co-workers also pointed out that there might be some other factors such as the attitude of staff towards hip protector would have certain effect on the compliance of hip protector though it was difficult to investigate (Hubacher and Wettstein 2001). In this study, there was some degree of variation of compliance across different hostels (28% - 48%), though they

were not significant. It was found that the hostel with the occupational therapist as the contact person and the highest staff to subject ratio had the highest compliance rate. Since the project staff was also an occupational therapist, the contact person being the same discipline may have positive effect on the attitude of the hostel staff towards this study, which in turn, has also positive effect on the use of hip protector by the hostel residents (Kurrle et al. 2004a). Forsen and co-workers also found that it would be an advantage in improving compliance of the hip protector if the project manager and the hostel contact person came from the same discipline (Forsen et al. 2004a).

4.7 Better acceptance rate of hip protector shown in the present study

The acceptance rate of hip protector in this study was found to be 66%, which was found to be higher than the mean acceptance rate of other studies, which is around 53% (van Schoor et al. 2002). The higher in acceptance rate might be a result of a well-planned education and risk counseling session before the provision of hip protector. Like other studies with acceptance rates over 60% (Parkkari et al. 1998, Kannus et al. 2000, Hubacher and Wettstein 2001), prior sessions including education to the hostel staff as well as the subjects were found to be beneficial in achieving higher acceptance and compliance rate. These education approaches were important in helping older people to build insight on their personal risk of fall and hip fracture and introducing the effectiveness of hip protectors, and hence facilitate the acceptance and use of hip protector by them.

4.8 Identification of factors influencing acceptance

In consideration of the factors determining acceptance, our study showed that only the characteristics of with 3 or more comorbidities and better performance in

activities in daily living associated positively with acceptance at marginal significant level. This might be a reason of the perception of at higher risk of fall and fracture for subjects with 3 or more comorbidities and better functioning in handling the wearing of hip protector for subjects with higher score in activities of daily living test. There were more subjects with recurrent history of fall or fractures and with higher level of education in the acceptance group. It might be easier for subjects who had past experience of recurrent fall and fractures to perceive their risk of fall and fractures again. Subjects with higher education level might be easier to understand the effectiveness of hip protector. These factors might associate with better acceptance of hip protector. The findings of this study agreed with a recent study on factors of comorbidites and fall history in positive association with hip protector acceptance among old age home residents (Cryer et al. 2006). However, our study did not show incontinence was a determinant of acceptance as shown in Cryer's study (Cryer et al. 2006), in contrast, higher percentage of subjects with incontinence was in the non-acceptance group though the difference did not reach significant level. Incontinence has been perceived as a problem of wearing hip protector involving frequent changing and positioning of the incontinence pads. Other studies also reported these problems associated with incontinence, particularly the concern of the old age home staff or the caregivers, who are responsible for the changing and laundering the hip protectors (Cameron et al. 1994, Butler et al. 1998).

Inter-hostel variation on the acceptance rate was also observed in this study. The acceptance rates in three out of the four hostels were higher than that in the literature while the other one had comparable value. The acceptance rate was found to be as high as 89% in one hostel. There may be two possible explanations for this. Firstly,

the education level of the subjects in this hostel was higher than the others, and education level was found to be with positive association with acceptance. Secondly, the discipline of the contact person of this hostel was an occupational therapist while other three hostels were nurses. This also congruent with other studies that project manager and the hostel contact person came from the same discipline would improve acceptance this may have positive effect on the attitude of the hostel staff and hence the residents (Forsen et al. 2004a, Kurrle et al. 2004a).

4.9 Percentage of protected fall was higher than mean compliance

It was also interested to observe that the percentage of protected fall was higher than the mean compliance rate across the study. This means that among the compliant subjects, the compliance rate was higher for those with history of fall than those do not during the study period. This revealed that subject with higher risk of fall might have higher compliance than those at lower risk of fall. This finding was also similar to that of a large trial done by Forsen and co-workers involving 1700 old age home residents in Northern Europe, who found the percentage of protective fall was also higher than the mean compliance (Forsen et al. 2004b). One possible explanation for this was that the staff in the hostel might give more frequent reminders to the subjects who had higher risk of fall to wear hip protector.

4.10 No hip fracture occurred while subjects wearing hip protector

The incidence of fall was found to be 19 falls per 100 person year in the present study. There was no significant difference in the incidence rate of the protected fall and unprotected fall. The wearing of hip protector neither increased nor decreased the fall incidence. There were no hip fractures occurred when the hip protector was being

worn compared with 2 hip fractures occurred when hip protector was not being worn. This finding also congruent with Parker's conclusion that hip fractures seldom occurred with hip protector is being worn (Parker et al. 2005). The hip protector was found to be safe to wear as it is not likely to increase fall and fracture incidence after wearing, however, the effectiveness of the hip protector on prevention of hip fracture needs a larger randomized controlled trial to prove.

4.11 Decreased fear of falling after wearing hip protector

Another favorable outcome of the hip protector was to improve the subject's confidence against fall during activities of daily living. Significant increase in confidence against fall in performing activities of daily living particularly those requires general mobility was shown after wearing of hip protector. The findings of this study were congruent with that from Cameron and co-workers who also showed the improvement of falls self-efficacy after the use the hip protector among the community-dwelling elderly (Cameron et al. 2000). As a consequence, the subjects may be more physically active and more independent in activities of daily living. This will be in turn associated with better functioning and quality of life (Tinetti et al. 1994b).

4.12 Limitation

One of the major limitations of this study was the limited sample size for detecting the effectiveness of hip protector on prevention of hip fractures. Although no hip fractures were occurred while the subjects wore hip protectors, the small sample size of this study provided insufficient power to prove its effectiveness. Cameron and co-workers found there was no significant effect for the hip protector in

prevention of hip fractures in their randomized controlled study (Cameron et al. 2001), however, this was due to their overestimation of hip fracture rates and the sample size was planned too small that the actual effect of hip protector on prevention of hip fracture might not be detected. Sample size of over 1000 subjects might be needed base on Cameron's study for detection of the effectiveness of hip protectors (Cameron et al. 2001).

Another limitation of the present study is the lack of other commercially available designs of hip protector for Chinese elderly for comparison with ours at the beginning of the present study. These resulted in that some of the important determinants of compliance such as the design of the hip protector were not investigated. Due to anthropometric difference, application of available products designed for Caucasians was not suitable for Chinese. Our findings showed that Chinese elderly are about 8% shorter in height, 12% smaller in waist size and 10% larger in waist to hip ratio than Caucasians (Taylor et al. 1998, Goodpaster et al. 2005), and fitting problems of the pants was foreseeable due to these anthropometric discrepancies. However, the result from the current study might be use to compare with future studies with different design of hip protector.

4.13 Recommendation

Compliance is an important issue for application of hip protector in prevention of hip fractures. There are several recommendations implied from the result of this study in order to improve the compliance and effectiveness of hip protector.

Firstly, it was found that a modification of the pad had positive effect on

compliance. However, modification of the design of pants was found to have no significant effect on compliance. It seems that that the chief problem of the pants - tightness, may not be easily solved, since the tight design of the pants is fundamental for holding the pads in place. In order to have breakthrough on the compliance, other designs of hip protector which do not require the subjects to wear a pair of pants for holding the pads may be necessary. Examples of such design may include those with the pads directly stick to skin or airbag design which provide instant protection when a fall is detected.

Secondly, reinforcing education program is important for both the acceptance and compliance of hip protector. The results of this study revealed that perceiving the hip protector as not useful or not necessary to use was the major factor for non-acceptance and non-compliance. Reinforcing the effectiveness and its relevancy to the subjects are important elements in hip protector program. It was also found that subjects with multiple history of fall or fracture were in positive association with compliance. Therefore, besides the education programs, individual counseling session is also important for explaining the individual risk of fall and fracture and how these could be prevented by wearing hip protector. These measures might have positive effect on hip protector compliance.

Finally, it is recommended to have fall risk assessments to screen out high risk subjects to wear hip protector rather than provide hip protectors to all the subjects. Factors associated with fall risk such as history of recurrent fall, history of fracture and especially hip fracture were found to be in positive association with compliance. It seems that factor associated with fall agrees with that associated with compliance.

Subjects with higher risk of fall tended to have higher hip protector compliance. Therefore, it is recommended to screen out subjects to have high risk of fall to wear hip protector as this will increase the effectiveness of the hip protector since for the same wearing time, the number of falls being protected might increase as compared to that of other subjects at lower risk of fall.

Conclusion

V. CONCLUSION

The present study investigated the mechanical properties, acceptance and compliance of Chinese old ladies who lived in local elderly hostels in using a modified hip protector. The hip protector was effective in attenuating 93% of the impact force in fall simulating mechanical test and the amount of force remaining was significantly below the fracture threshold of proximal femur of old ladies. Although the hip protector was modified in several concerns including fitness, climate and appearance, only 66% of subjects accepted to wear hip protector and the mean compliance across the study period was only 40.4%. However, the night time compliance was better than some of the foreign studies.

It was found that subject's perception on the usefulness of hip protector and its relevance to themselves as well as its design were the major determining factors for acceptance of hip protector. For the determinants of compliance in using hip protector, subject's feedback on comfort to wear and gaining of confidence against fall in daily activities after wearing hip protector were the major determining factors of compliance. Being hot and humid were the major barriers for the use of hip protector in Hong Kong. Subjects with repetitive history of fall and fractures tended to be those who were more compliant in using hip protector.

Acceptance and compliance of hip protector remains the major issue of hip protector in determining its effectiveness. In order to improve the acceptance and compliance, a non-pant design of hip protector, which is less discomfort to be used under hot and humid climate, has to be developed and a good facilitation program

including education and counseling are necessary, especially in the early phase of the application.

Appendix

Appendix 1: Protocol on study of the compliance of Hip Protectors

1. Title of Project

Compliance study of a newly designed Hip Protector for Chinese older ladies

2. Investigators

Prof Leung Kwok-Sui (principal investigator) Dept of O&T CUHK
Mr Sze Pan Ching (contact person) Dept of O&T CUHK

Tel / Fax: 26322756 / 26324618
Email: szepc@ort.cuhk.edu.hk

3. Aim of the Study

To evaluate the compliance and acceptance of hip protector among Chinese older ladies

4. Study proposal

Background
It has been proven the effectiveness of hip protector on prevention of hip fractures. Mechanical study has shown that hip protectors with a convex hard shield and soft cushioning materials design can attenuate the impact force to the hip bone in an occasion of fall to a level which is significantly below the fracture threshold of the hip bone (Kannus *et al*, 1999). A large randomized clinical trial demonstrates the reduction of 60% risk of hip fractures with the use of hip protectors among older people (Kannus *et al*, 2000). Other local and overseas studies also show similar effects (Woo *et al* 2003; Parker *et al*, 2004).

However, compliance and acceptance are the major problems of hip protectors and there was only a median compliance of 57% reported in studies (van Schoor NM *et al*, 2002). Studies have identified some determinants of the compliance of hip protectors including the designs of hip protectors and the characteristics of users (van Schoor NM *et al*, 2002; Hubacher *et al*, 2001; van Schoor NM *et al*, 2003) but the results remain inconclusive and the application of these results to Chinese elderly needs further research. Study has also proven the cost-effectiveness of hip protectors in prevention of hip fractures and improvement of quality of life (Singh *et al*, 2004). From literature, we know that if the hip protectors are mechanically sounded, and are accepted and worn by the user, hip fractures seldom occur. It will be a cost-effective way to prevent the most disabling condition, hip fractures, among elderly, especially for those with poor bone quality.

An improved design for Chinese older ladies has been produced by us. Our design is made according to the body figures of the old ladies; use a better cushioning material (silicon) to improve comfort. Our design is also smaller and slimmer when compared with current products so that it is more appealing. Our hip protector has been proved mechanically to reduce the impact force significantly below the fracture threshold of the hip.

Method

Clinical trail will be performed among 180 old ladies aged over 70 who are living in old age homes in Hong Kong on compliance and acceptance of our hip protector. Baseline measurements including assessment of muscle power, mobility and medical histories will be taken before the start of the trials. Hip protectors will be provided to all the old ladies who are willing to wear. Educational talks on the importance and the use of hip protector will also be provided to them. All the old ladies will be followed up for 12 months on their compliance, incidence of fall or fractures and their feedback on the use of hip protectors. The investigators will monitor the wearing of hip protectors throughout the trial.

Outcome Measures
Primary outcomes: acceptance and compliance
Secondary outcomes: falls efficacy, incidence of fall and fracture, determinants of compliance

Impact of the study:
The study will provide valuable output in the determinants of acceptance and compliance of hip protectors for Chinese elderly. It will be essential for the improvement of current design of hip protectors for Chinese elderly so that more elderly with high risk of fall and fractures will use the hip protectors.

5. Details of study

Period of Study:
12 months

Consent form:
Please see attached

Participants:

Inclusion criteria

- ☐ Female OAH residents
- ☐ Aged 70 or above
- ☐ Mobility: better than wheelchair-mobile
- ☐ Standing ability: unaided

Sample size:

178 (including subjects who do not accept the use of HP, approximate sample size for acceptance group: 100)

Study period:

12 months

Outcome measures:

Primary outcome: Acceptance, Compliance (Percentage of people and time of HP wearing)

Secondary outcome: Incidence of fall and related injuries, confidence against fall, determinants of compliance

Measurement tools:

Acceptance and compliance: Acceptance and compliance chart

Incidence of fall and related injuries: case report form

Reason for non-acceptance/compliance, problems on wearing hip protector: questionnaire

Characteristics of subjects	*Tools*
Age, medical history, education level, history of fall and fracture.	Questionnaire
ADL function	Barthel Index-100
Mobility and gait	Time up and Go test
Functional grip and pinch	Jamar and Pinch gauge
Cognitive level	Mini-Mental State Exam
Confidence against fall	Activity-specific Balance Confidence Scale

Measurement methods:

Acceptance:

Counting the number of subjects who accept to wear hip protectors over the total number of subjects

Compliance:

Weekly random check by staff from OAH using a monthly updated compliance chart with checking dates and times for each participant, 8 episodes for each participant will be checked in each month

Incidence of fall and fracture:

Case report by OAH staff (date, time, venue, level of injury)

Characteristics of subjects and problems of wearing HP:

Face to face interview

Frequency of measurement:

Baseline: characteristics of subjects, acceptance rate)
Beginning of each study month: compliance, incidence of fall and injuries of subjects
At the end of the 1st, 6th and 12th month after wearing HP: problems of wearing HP

Intervention:

Staff training program: one hour training program to all the OAH staff involved. The program includes introducing the rationale for the study, reviewing the effectiveness of the hip protector, and briefing on the methodology of the study.

Education program: one hour education program on facilitating the elderly to wear HP is specially designed for all the subjects. The program will focus on impressing them the commonness and seriousness of hip fracture, how the HP will help them to prevent hip fracture and the correct use of HP.

***Provision of Hip protector*:** one pack of hip protectors including 3 pairs of pants and 1 pair of pads will be provided to all the subjects who accept to wear HP.

Training session on wearing of hip protectors: one hour training session will be provide to all subjects who accept to wear HP and all the staff who is responsible for the monitoring of the wearing of HP by the subjects. The objective of the training session is to make sure the subjects are able to wear and remove the HP safely and correctly. Laundry method will be also taught during the session.

Individual counseling: The aim of the counseling is to reinforce the acceptance and compliance of wearing of the HP by the subjects. During the individual counseling session, individual risks of fall and fracture will be reported to the subjects and emphasize the protection of the HP, recommendations to reduce risk of fall and fracture will be also provided.

- ☐ At the 1st, 6th and 12th month, to all the subjects wearing hip protectors
- ☐ To subjects with compliance lower than 70% in the previous 2 weeks upon biweekly review.

Meetings with staff

Biweekly short meetings with all the staff involved to collect compliance chart, get their feedback on the wearing of HP by the subjects and encourage their continuous input to the project.

***Group Sharing and Education*:**

Monthly group sharing will be provided to all the subjects in small group of group size about 10-15 people. During the session, education on the protective mechanism of HP will be reinforced. Subjects with high compliance rate will also be invited to share the experience of using HP so as to encourage other subjects.

Summary of procedure

1. Staff training at OAH
2. Subject selection by the OAH
3. Education seminar
4. Consent, baseline measurement,
5. Individual counseling session for subjects who do not accept the wearing of HP
6. Provision of HP and training session on wearing of HP
7. Checking of compliance
   - ☐ Twice per week by OAH staff
   - ☐ Once per week by research staff for monitoring purposes
8. Biweekly short meeting with OAH staff
9. Biweekly individual counseling for subjects with compliance rate below 70%
10. Monthly group sharing and education program
11. Individual counseling session for subjects who wears HP at the 1st, 6th and 12th month

Reference:

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Appendix 2 Content of education program for hostel staff and elderly subjects

Education Program
Content
Epidemiology consequence of hip fractures among elderly
Consequence of hip fractures
Effectiveness of hip protector in prevention of hip fractures
People who need to wear hip protector
Practical issues in wearing of hip protector - wearing regime - method of wearing and removing hip protector safely - laundry method - possible undesired outcomes after wearing hip protector and solutions
*Literature review on effectiveness of hip protector
*Introduction on the research study - study flow (outcome measures, study period, assessments etc.) - role and importance of staff
*Method of data collection, record and report
*Possible problems and solutions
Question and Answers

* for related hostel staff only

Appendix 3: Information sheet for subjects

髖關節保護墊使用計劃

香港中文大學矯形外科及創傷學系

研究小組負責人： 梁國穗教授 (Prof. Leung Kwok-Sui)
香港中文大學矯形外科及創傷學系

前言

長者骨折是嚴重的臨床醫學問題，當中尤以髖關節爲甚。目前西方國家已開始研究髖關節保護墊對預防髖關節骨折的臨床應用，並取得顯著效果。但髖關節保護墊在東方人的接受程度及應用方面，則需進一步研究。有見及此，香港中文大學矯形外科及創傷學系爲東方人設計了一套特別髖關節保護墊，並將會進行一項使用計劃，以試驗新設計之髖關節保護墊之接受及使用程況，希望能把有效的髖關節骨折預防方法帶致中國社會。

什麼是髖關節保護墊?

髖關節保護墊可分爲保護褲及保護墊兩部份〈見下圖〉。保護褲其實是一條特別設計之棉質內褲，褲子兩旁分別有兩個袋子用以裝載保護墊。保護墊是一橢圓形而中間程拱形之硬墊，主要由外層之硬膠及內層之軟墊組成，其作用是緩衝跌倒時對髖關節的撞擊力，從而減低骨折機會。由於跌倒意外可發生在日間及夜間，因此髖關節保護墊亦須二十四小時穿著才可確保其功效。

此項研究計劃的重要性

基於眾多的外國研究報告結果，我們深信髖關節保護墊對預防髖關節骨折是有效果的。我們這個研究計劃的目的就是要証明改良後的髖關節保護墊是可以應用在中國人身上，並爲髖關節骨折的預防工作擴展新元素。

髖關節保護墊有沒有損害性?

其實使用髖關節保護墊是***不會引起任何身體上的損害***。此外很多外國的研究均***沒有証據顯示***髖關節保護墊會引起疼痛及後遺症。

使用計劃如何進行?

參加此研究計劃的長者需要接受每天二十四小時穿著髖關節保護墊，每位參加者會獲發三條保護褲以供替換。整個使用計畫將會持續12個月。

保護褲

保護墊

Appendix 4 Consent form

香港中文大學矯形外科及創傷學系

髖關節保護墊使用計劃

參加者同意書

下述簽名者

姓名 _____ 身份證號碼_____ 編號 _____

我在此聲明自願參加髖關節保護墊使用計劃：

一）我已經完全瞭解及自願參予此計劃。

二）我明白參加者須接受為期 12 個月的使用計劃。我願意依照計劃每日穿著髖關節保護墊。

三）我明白穿著髖關節保護墊為減低髖關節骨節機會及對身體無副作用。

四）我明白此計劃是怎樣進行的。

五）我有權提出有關此計劃的各種問題，而且我所提出的問題會得到完滿的解答。

六）我明白有權隨時退出此計劃，我亦明白醫護人員有權決定我不適宜完成此計劃而須要停止。

七）我提供的資料準確無誤，并有可能用作醫學研究用途。

八）我證明我已經完全瞭解這份同意書的內容。

九）所有參加者資料絕對保密。

十）如有任何問題，可於辦工時間內致電 2632-2756 向施先生查詢。

參加者姓名: _____ 簽名: _____

茲證明上述自願者完全了解他們所參加的計劃，並表示同意書正確無誤。

工作人員簽名: _____ 日期_____

Appendix 5: Ethical Approval

香港中文大學醫學院
Faculty Of Medicine
The Chinese University Of Hong Kong

醫院管理局
新界東醫院聯網
Hospital Authority
New Territories East Cluster

Joint The Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee
香港中文大學–新界東醫院聯網 臨床研究倫理 聯席委員會

Secretary of the Clinical Research Ethics Committee c/o Centre for Epidemiology and Biostatistics,
Faculty of Medicine, The Chinese University of Hong Kong, 5th Floor, Postgraduate Education Centre, Prince of Wales Hospital
Tel : (852) 2252 8717 Fax : (852) 2646 6653

To: Prof. Kwok Sui LEUNG (Principal Investigator)
Dept. of Orthopaedics and Traumatology
Prince of Wales Hospital

6 October 2005

Renewal of Ethics Approval

CREC Ref. No.:	**CRE-2004.331**
Date of Renewal:	**06 October 2005***
Protocol Title:	**Acceptance and Compliance of A Newly Designed Hip Protector for Chinese Older Ladies**
Investigator(s):	**Kwok Sui LEUNG and Pan Ching SZE**

I write to inform you that ethics approval has been renewed for the captioned study in accordance with document(s) stated as per the approval letter dated 05 October 2004.

This ethics approval* will be valid for 12 months. Application for further renewal can be made by submitting the Renewal and Research Progress Report Form to the CREC. It will be much appreciated if the completion of the project will be reported to the Committee in due course.

The Joint CUHK-NTEC Clinical Research Ethics Committee serves to confirm that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations, HA and University policies.

(Prof. Joseph Lau)
Secretary, Joint CUHK-NTEC
Clinical Research Ethics Committee

JL/ci

Appendix 6: Compliance chart

姓名	3月21日am	3月24日am	3月29日pm	4月1日pm	4月7日am	4月11日pm	4月14日am	4月18日pm
[redacted]								

am = 午飯前後　　pm = 睡前　　M4

請負責之職員於指定的日期及時間檢查每一位名單上之舍友是否有穿著保護褲，並在空格上填上✓(有穿著)或×(沒有穿著)
檢查方法：輕拔各舍友髖部兩側之位置以檢查舍友是否穿上保護墊

Appendix 7: The Activities-Specific Balance Confidence (ABC) Scale

/項目	**Level of Confidence /** 信心程度 **0-10**
1. Walking around the house 在屋內行走	
2. Walking up and down stairs 上落樓梯	
3. Picking up slipper/something from the floor 從地上檢拾物件	
4. Reaching at your eye level 在視野範圍內伸手拿東西	
5. Reaching while on your tiptoes 踮著腳伸手拿東西	
6. Reaching while standing on a chair 企在椅上伸手拿東西	
7. Sweeping the floor 掃地	
8. Walking outside to a nearby bus stop 行出屋外往巴士站候車	
9. Getting in / out of a bus 上落交通工具如巴士	
10. Walking across a parking lot 在停車場內行過	
11. Walking up and down a ramp 在斜坡上行走	
12. Walking in a crowded mall 在擠迫的商場行走	
13. Being bumped while walking in a crowd 在人群中走動時被碰撞	
14. Using an escalator while holding the railing 需要使用扶手來上落自動電梯	
15. Using an escalator without holding the railing 不需要使用扶手來上落自動電梯	
16. Walking on slippery floors 在濕滑的路面上行走	
Total score 總分:	**/ 160**

Appendix 8: Bathel Index (Modified)

Name:_____ Case No. _____

Date:_____ Date: _____

Function	**Score**				
Bathing	0	1	3	4	5
Feeding	0	2	5	8	10
Dressing	0	2	5	8	10
Toilet use	0	2	5	8	10
Personal hygiene	0	1	3	4	5
Transfer	0	3	8	12	15
Ambulation	0	3	8	12	15
	N	S	Q	F	W/C
Climbing stairs	0	2	5	8	10
Bowels	0	2	5	8	10
Bladder	0	2	5	8	10

Total: _____

Independent level:

- ☐ Total dependence (0-20)
- ☐ Severe dependence (21-60)
- ☐ Moderate dependence (61-90)
- ☐ Slight dependence (91-99)
- ☐ Independent (100)

Appendix 9 **Mini-Mental State Examination**

Name_____ **Centre** _____

ID _____ **Date** _____

Domain	Items`	Score
Orientation to time	Year (1) Month (1) Date +/- 1 (1) Season (1) Day +/- 1 (1)	/5
Orientation to place	HK/KL/NT (1) District (1) Estate (1) Centre (1) Floor (1)	/5
Registration of three words	Apple; Newspaper; Train (@1) 【蘋果】、【報紙】、【火車】	/3
Attention and Calculation	Subtraction test of 7 from 100 for 5 times or Recall 42731 in reverse (5)	/5
Recall of words	(3, @1)	/3
Language	Naming, 鉛筆, 手錶 (2) Repeating Sentence, 姨丈買魚腸 (1) Follow 3-step command (3) Comprehension (1) Saying a complete sentence (1)	/8
Visual Construction	(1)	/1
	Total	/30

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1. **Sze PC**, Lam PS, Chan J, Leung KS. A primary prevention programme for older people in Hong Kong. Br J Community Nurs 2005; 10: 166-71

2. Leung KS, **Sze PC**, Cheung WH, Tam KF, Ng WK, Chu LP. Compliance rate of a modified hip protector among old age home residents in Hong Kong. China Bone and Joint Decade – International Osteoporosis Conference. Hangzhou China, 2005 (poster presentation)

3. Lam PS, **Sze PC**, Chan T, Leung KS. Effectiveness of a one-year fall prevention community model program in Hong Kong. China Bone and Joint Decade – International Osteoporosis Conference. Hangzhou China, 2005 (poster presentation)

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5. Lam PS, Lam TP, **Sze PC**, Lui PPY, Leung KS. Fall related injuries in the elderly population: A study of 3105 cases seen at a regional hospital. National Symposium on Osteoporosis and Bone Disease 2005 (2005 年全國骨質疏鬆與骨關節病研討會), Shenzhen, China, 2005 (Oral presentation)

6. **Sze PC**, HY Lam, KS Leung, Cheung WH, Wong WK. Readmission rate of older people with a history of fractures as a result of fall-related injuries in Hong Kong. 25th Annual congress of the Hong Kong Orthopaedic Association, Hong Kong, 2005. (Oral presentation) HK J Orthop Surg 2005; 9(suppl): 67

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P32: Analyze Peri-menopausal Women's Vertebral Morphous by DXA

利用双能X线骨密度检测仪对围绝经期妇女椎体形态的分析

YU Zhifeng, HU Xiliang, DAI Kerong
于志锋，胡锡良，戴克戎
上海交通大学附属第九人民医院骨科 上海 200011

Objective Analyze peri-menopausal women's vertebral morphous by using the technology of instant vertebral assessment (IVA).
Materials and Methods Measure 31 peri-menopausal women's vertebral morphous and their BMD of femoral and vertebral, and compare the results with the normal women's.
Results The BMD and the average height of vertebral in peri-menopausal group is below those of the normal group. There is no distinctive difference among femoral BMD and the ratio of the change of vertebral.
Conclusion The change of peri-menopausal women's vertebral morphous may be related to the decline of their BMD. It may also lead to osteoporotic frature.
Key Words Instant vertebral assessment (IVA); Peri-menopausal period; BMD

P33: Teriparatide After Treatment Six Months and Bone Formation

特立帕肽应用六个月后对骨形成的影响

A Bazarra-Fernández*, MA Bazarra-Castro**
Department of Ob Gin. Juan Canalejo University Hospital. La Coruña*. Medicine. University Santiago. Santiago**. Spain.

Background Bone turnover is very slow, only about half skeleton is brokendown and rebuilt 10 to 12 years. It may take several years following the start of drug therapy for a significant change in bone quality to become evident.
Objective To investigate bone remodelling markers on treatment with teriparatide after six months treatment.
Materials and methods 16 women who were 45 to 80 years old has been recruited. They were assigned to two groups according age, 45-65, 66-80. Bone density was determined by DEXA. They were given subcutaneous teriparatide injection of 20 microg/day for three and six months. Fasting blood and urine samples were collected at baseline, at three and six months. Calcium supplement was 1500 mg per day with 0.266 mg vitamin D twice a week.
Result In 45-65, 66-80 group the mean BMD was T-score -1.8 and -3.20. At base line fasting blood and urine sample mean: Serum calcium 9.1; 8.9 mg/dl, 25-hydroxyvitamin D 16; 12 ng/ml, alkaline phosphatase173; 162 U/L bone-specific alkaline phosphatase 26.3%; 23%. PID 9;15 nM PYD/mM creatinine, urinary calcium 64; 240. At three months: Serum calcium 9.9; 9.3 mg/dl, 25-hydroxyvitamin D 68; 88 ng/ml, alkaline phosphatase193; 180 U/L bone-specific alkaline phosphatase 45.3%; 32%. PID4.8; 8.7 nM PYD/mM creatinine, urinary calcium 189; 309. At six months with seven and six cases the results are similar in relation to both groups.
Conclusion Bone formation is clear with teriparatide and over all in osteopenia although its quality is not evident. Increasing of bone formation is different in both groups. The bone development is not continuous but in cycle basis because of we think one cycle basis approach is needed to be found with teriparatide and inhibitors of osteoclast-mediated bone resorption of short action without deposit for long in bones. So, there will not be interference between both drugs, it would be given longer as for the body to chemical decontamination avoiding side effects and beginning treatment in patients younger before fractures, recovering lost bone and after continuing with antiresorptives.

P34: Evaluation of the Estrogenic Activity of Oriental Plants with Implications for its Role on Bone

东方植物中雌激素作用对骨作用的评价

Mi-Kyung Park[1], Mee-Ra Rhyu[2], and YoungJoo Lee[1]
1. College of Engineering, Institute of Biotechnology, Department of Bioscience and Biotechnology, Sejong University, Seoul, Korea.
2. Korea Food Research Institute, Seongnam-Si, Gyeonggi-Do, Korea

Objective We have aimed to study the estrogenic activity of the extracts of Panax ginseng, Panax notoginseng, Curcuma aromatica, Curcuma domestica, Schizandra chinensis and Lycopus coreanus.
Materials and Methods The phytoestrogenic activity was characterized in a transient transfection system, using estrogen receptor isoforms and estrogen-responsive luciferase plasmids, in COS monkey kidney cells. Induction of expression of the progesterone receptor, pS2, and estrogen receptor were measured in MCF-7 cells. Increase in alkaline phosphatase activity, one of the osteoblastic phenotype markers, was determined in osteoblast-like MC3T3-E1 cells.
Result We have examined the possibility that the extracts of Panax ginseng, Panax notoginseng, Curcuma aromatica, Curcuma domestica, Schizandra chinensis and Lycopus coreanus act by binding to the estrogen receptor. Ginsenoside-Rb1 from Panax ginseng and extracts of Schizandra chinensis activated transcription of estrogen-responsive luciferase reporter gene in MCF-7 breast cancer cells and CV-1 kidney fibroblast cells transiently transfected with ERa or ERβ at 10 uM concentration. This activation was inhibited by specific estrogen antagonist, ICI 182,780. G-Rb1 and extracts of Schizandra chinensis activates endogenous estrogen-responsive genes.
Conclusion In this study, we characterized the in vitro estrogenic activity of Panax ginseng, Panax notoginseng, Curcuma aromatica, Curcuma domestica, Schizandra chinensis and Lycopus coreanus, providing a scientific foundation for potential clinical development.

P35: Compliance Rate of a Modified Hip Protector Among Old Age Home Residents in Hong Kong

改良髋部保护器在老年人中应用的依从性

Kwok-sui Leung, Pan-ching Sze, Wing-hoi Cheung, Kam-fai Tam, Wai-kin Ng, Lin-pik Chu
Department of Othopaedics and Traumatology, The Chinese University of Hong Kong, HKSAR

Objective Poor compliance is the major obstacle for hip protector (HP) to be an effective approach to prevent hip fractures. Uncomfort and poor fitting are the major reasons of non-compliance. This study evaluated the force attenuation properties of a modified HP and its compliance among old age home residents in Hong Kong.

Materials and Methods A modified design HP was developed with 50% smaller in size when compared to western designs. Silicon padding was also added to improve comfort. Anthropometric consideration was made to fit the body figure of the local population. Force attenuation property of the HP was tested by dropping a weight from a height which simulates the physical condition of fall to a force plate (Kistler 9285) with and without placing the HP. One hundred and eighty ambulant female residents with age 70 or above were recruited from four local old age homes (OAH) for this compliance study of the modified HP. Compliance rate was recorded by OAH staff in unannounced checks as scheduled by the investigators for a one-year period.

Result The impact force in fall simulation study was significantly decreased ($p<.001$) in the presence of HP, and was found to be significantly lower than the fracture threshold of proximal femur of old ladies (3100N, $p<0.001$). There were 64% of subjects accepted to wear HP with average compliance rate 55.8% (night 55.4%, day 56.2%) for the first six months. The major reasons for non-compliance were clumsiness and hotness. There were more subjects with fracture history and recurrent falls in the high compliance group (average compliance rate>70%) although the difference was not significant.

Conclusion HP was found to be effective to prevent fracture in laboratory study. Although several modifications have been made, more measures like education, encouragement to family members as well as exploring new designs like airbag HP should be made to further increase compliance rate.

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P36: The Effects of Anti-resorptive Agents (Raloxifene, Estrogen, and Alendronate) on the Processes of Fracture Repair

骨吸收抑制剂（雷诺昔芬，雌激素，阿仑膦酸钠）对骨折愈合过程的影响

CAO Yongping[1,2], Satoshi Mori[2], Tasuku Mashiba[2], Michael.S. Westmore[3], Yanfei Ma[3] Masahiko Sato[3] Hiromichi Norimatsu[2]
曹永平[1,2], Satoshi Mori[2], Tasuku Mashiba[2], Michael.S. Westmore[3], Yanfei Ma[3] Masahiko Sato[3] Hiromichi Norimatsu[2]
1. Dept. of Orthopedic Surgery, First Hospital of Peking University, China
2. Dept. of Orthopedic Surgery, School of Medicine, Kagawa University, Japan
3. Lilly Research Laboratories, Indianapolis, 46285, USA
1. 北京大学第一医院骨科
2. 日本香川大学医学部整形外科
3. Lilly Research Laboratories, Indianapolis, 46285, USA

Objective We investigated the effects of inhibitors of bone remodeling- estrogen, raloxifene, and alendronate- on the processes of fracture repair in ovariectomized rats.

Materials and Methods 140 female SD rats at 3-months of age were either ovariectomized or sham-operated and divided into five groups: Sham control, ovariectomized control (OVX), estrogen (0.1 mg/kg, 17-ethynylestradiol, EE2), raloxifene (1.0 mg/kg, Rlx) and alendronate (0.01 mg/kg, Aln) groups. Four weeks later, a set of pre-fracture controls were euthanized, while bilateral osteotomies were performed on femoral midshafts and fixed with intramedullary stainless wires for the surviving animals. Vehicle (Sham and OVX) or appropriate compounds were administered to the surviving animals until 6 weeks and 16 weeks post- fracture. Fracture repair was evaluated by x-ray radiography, micro-CT, biomechanical testing, and histomorphometry.

Result At 6 weeks post-fracture, Aln and OVX had significantly greater body weights and larger calluses than the other groups. Sham and OVX calluses had the highest ultimate load, while EE2 and Rlx had lower ultimate load with Aln intermediate between the sham and OVX groups and the EE2 and Rlx groups. However, the material properties (Young's Modulus and ultimate stress) for the Aln calluses were significantly below Sham levels. Histomorphometry showed significantly less lamellar bone for Aln calluses, with lower osteoclast surface, mineralized surface, mineral apposition rate, and bone formation rate compared to OVX. By 16 weeks post-fracture, OVX calluses were significantly smaller than at 6 weeks, while the dimensions for Aln had not changed. After 16 weeks, EE2 and Rlx had similar biomechanical properties, which were similar to, but not identical to, Sham. Aln increased stiffness by 45% relative to Sham due to the large calluses, but had inferior material properties compared with all other groups. Histomorphometry showed that EE2, Rlx and Aln significantly reduced osteoclast surface and number; but Aln was more efficacious in inhibiting mineralized surface, mineral apposition rate and bone formation rate than EE2. Aln calluses had the lowest amount of lamellar bone (lamellar bone/callus area), the largest amount of mineral (BMC), and the best visibility of the original fracture line, compared with all other groups.

Conclusion OVX-stimulated bone turnover resulted in the fastest progression of fracture repair after 16 weeks, which was most delayed with alendronate treatment consistent with marked suppression of bone resorption and formation activity. Estrogen and raloxifene had similar effects that were generally similar to Sham, indicating that mild suppression of bone turnover with these agents has insignificant effects on the progression of fracture repair.

P37: Long-term Bisphosphonate Administration and Microdamage Accumulation

双膦酸盐的长期治疗与骨微损伤的积聚

CAO Yongping[1,2], Satoshi Mori[2], Tasuku Mashiba[2], Hiromichi Norimatsu[2]
曹永平[1,2], Satoshi Mori[2], Tasuku Mashiba[2] Hiromichi Norimatsu[2]
1. Department of Orthopedic Surgery, First Hospital of Peking University, Beijing, China.
2. Department of Orthopedic Surgery, Kagawa Medical University, Kagawa, Japan
1. 北京大学第一医院骨科
2. 日本香川大学医学部整形外科

Objective It has been reported that microdamage is accumulated by bisphosphonates(BPs) treatment, while increases bone mass and decreases fracture incidence. But cause-effect relationships of these findings are still unknown. This study aimed to evaluate the change of bone turnover, microdamage accumulation and mechanical strength of the dog's rib following 3 years BPs treatment.

Materials and Methods 29 dogs, 1 year old, were divided into three groups: control group (n=10) was given lactose, low-dose group(0.3mg/kg/day, n=10) and high-dose group(0.6mg/kg/day, n=9) were treated with incadronate disodium (YM-175, Yamanouchi Pharm. Japan). All dogs were treated for three years. pQCT measurement and

that exist in the nutrient condition and physical stature's growth in time and improving the nutrient condition from now on.

Materials and Methods Measuring avoirdupois、stature、rounds of head and rounds of chest , surveying the nutrient condition and physical stature's growth of 500 ex-children of school age who are two to five years old and are checked in health care section of women and children in New Country distriction's prevention of epidemics station before go to Day nursery .

Result Each aging team's nutrient condition and physical stature's growth are shown to be no obvious difference (P>0.05) , but excepting that there is no obvious difference between stature and nutrient condition (P>0.05) , there is obvious difference between avoirdupois , rounds of head , rounds of chest and nutrient condition (P<0.05).

Conclusion By this survey , we find that physical stature's growth of ex-child of school age in New Country distriction is well , but the ratio of obesity is high (19.2%) .

Key Words ex-child , nutrient condition , physical stature's growth.

A35: A Tentative Exploration on the Relation Between Infantile Feeding and Development of Intellectual Ability
婴幼儿喂养与智能发育初步探讨

TU Erxunjiang, SUN Juanjuan
吐尔逊江, 孙娟娟
Teaching and researching section of Nutrition and food hygiene, public health department , Xinjiang medical university, 830054
新疆医科大学公共卫生学院营养与食品卫生学教研室（新疆乌鲁木齐市 830054）

Objective We tentatively explored the factors that affect the development of intellectual ability by surveying about the Uygur nationality (Uygurs) 、 the Han nationality and the Kazak nationality (Kazaks)infantile nutritional status and intellectual development in order to provide scientific foundation for developing weaning food that suit to different national infantile dietary habits.

Materials and Methods The Uygurs、Hans and Kazaks'infants who lived in Tulupang、 Vrvmqi、 Hutubi district was choosed and we surveyed 454 infants.We inquired and recorded by the method named one card for one people and measured the intellectual ability by the method named Denver Deve Lopmental Screening Text.

Result (1) The condition of three national infantile supplementary food added is that the kinds of supplementary food among three nations are quite different:Kazaks takes milk product as dominant food and meat 、 vegetables and fruits are added after one year old ;Ugyurs takes a little meats as main food, while the Hans takes eggs and grains as dominant food .(2) The comparision of the time three national infant beginning to add supplementary food: Hans' <Uygurs' <kazaks',there is great statistical significance (P<0.01).(3)The condition of development of intellectual ability: The marks of the three national infantile intellectual ability test is that: Hans'>Uygurs'>kazaks',only in 2-3year old group Kazaks'> Uygurs', there is statistical significance (P<0.01).(4) After T test, the time beginning to add supplementary food is great significance to development of intellectual ability on statistic(P<0.05).

Conclusion It is good to development of intellectual ability that parents improve mother and the infantile nutritional condition and add supplementary food (weaning food) in early age.

A36: Effectiveness of a One-year Fall Prevention Community Model Program in Hong Kong
社区内一年预防跌倒的效果

Lam PS, Sze PC, Chan T, Leung KS
Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Hong Kong SAR

Objective Falls are common and serious injury among elderly. These lead to serious consequences of medical, physical, and social burden. Osteoporotic fracture of femur was the 4th major cause of bed occupancy in public hospitals with 150,000 bed days. This program aims at reducing number of falls which in turns reduce the osteoporotic fractures among elderly in Hong Kong.

Materials and Methods A Community-based Fall Prevention Program was established in one elderly service organization in Hong Kong in 2003. It involves 188 elderly participants accomplishing the fall risk screening. A series of community interventions were prescribed to different risk groups accordingly, e.g. exercise classes, regular tutoring, home assessments and home modifications, and referrals to fall prevention clinic for more detailed medical and balance assessments. Each of the participants had been prescribed a fall calendar to record fall incidences. Fall records were collected by research staff every month for a year as the primary outcome. Balance and subjective confidence scale were assessed as the secondary outcomes. Paired t-test was used to compare the differences in fall incidences, balance performance, self rating confidence scale pre- and post- 1-year intervention.

Result 116 elderly participants finished the 1-year fall prevention program. The average fall incidences were significantly dropped from 0.97 to 0.31 (p<0.001). Among the 63 fall prevention clinic attendants, the balance showed significant results: Berg Balance scale scores improved (p=0.0033); Backward directional control improved (p=0.002), and backward degree of movement increased (p=0.04) in voluntary motor control of SmartEqui test of balance. Activities-specific Balance Confidence Scale showed significant improvement in self-rating of confidence in daily activities (p=0.0036)

Conclusion It showed promising results of the 1-year community fall prevention program in reducing number of falls and improving balance. The ultimate goal of reducing number of osteoporotic fractures can be achieved. Therefore, the 1-year community fall prevention program is successful and adaptable running in Chinese community. Sustaining effect of this program is now being investigated.

Key Words SK Yee Medical Foundation, BMCPC, AADO community service fund

A37: Can Milk Prevent Osteoporosis?
牛奶能防止骨质疏松吗？

JIANG Liangduo[1], WANG Shuli[1], ZHOU Lizhen[2]
姜良铎[1], 王淑丽[1], 周丽珍[2]
1. **Dongzhimen Hospital of Beijing University of Traditional Chinese Medicine postalcode 100700**
2. **Dongfang Hospital of Beijing University of Traditional Chinese Medicine postalcode 100078**
1. 北京中医药大学东直门医院 邮编 100700
2. 北京中医药大学东方医院 邮编 100078

2005年全国骨质疏松与骨关节病研讨会与讲习班论文集

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疼痛。其显著的止痛效果和明显的微创优点值得临床推广应用。

3.3 PVP并发症的预防　PVP的严重并发症是骨水泥外漏引起神经损伤或肺栓塞。采取积极的预防措施有助于防止并发症的发生。防止骨水泥渗漏的最可靠的方法是在C臂机密切监测下缓慢注射，一旦发现不渗漏，立即停止。另外，椎体压缩2/3以上，穿刺针易进入椎间隙，造成骨水泥漏出，此类病人宜做PVP[3]。宜选择能耐受1~2 h俯卧位、无重要脏器功能不全、有临床症状的上述良、恶性病变，且经X线片和CT扫描示椎体后缘完整者。而对于年老体衰、重要脏器功能差、椎体骨质破坏严重、后缘不完整者应列为禁忌。注入造影剂验证：穿刺后，从穿刺空针内注入欧乃派克显影剂1~3 mL，透视下观察造影剂是否位于椎体内。若造影剂向椎体后缘外溢，且超过椎体后缘，则应放弃注入骨水泥，终止手术。若造影剂向前方外溢可经椎体血窦向椎体周围静脉回流方向显影，则宜经空针填入少许明胶海绵屑沫于椎体血窦内，并使骨水泥稍干至稠糊状再缓慢注入椎体内，边透视边注入，使稍干的骨水泥不致于进入血管循环内。

3.4 有关存在问题的讨论　病变椎体压缩骨折后，其本身的屏蔽受到破坏，但椎体骨压是否完全存在？其骨折是否存在不稳定的因素：椎体穿刺后是否对椎体的内压有一定的减压作用，同时注入骨水泥使骨折的稳定性加强，使其疼痛也有所缓解：目前还未见有关报导PVP前病变椎体的内压测定与疼痛的分析报告。骨水泥身身在体内不能生物降解是其一大缺陷，应用磷酸钙及羧基磷灰石骨水泥能否代替PMMA尚在研究中，据国外文献报导[4]，注射性锶羧灰石的钙含量、刚度、强度以及与骨的相溶性均优于PMMA，但其原子的含量高，有一定的放射性，能否广泛应用于临床尚待于进一步研究。

总之，PVP的止痛效果近期非常理想，严格掌握适应症，对于解除受此类疾病折磨的患者无疑是一个佳音。应该看到PVP目前还是一症状治疗，解决原发病，还需全面系统综合治疗。

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香港居家老年人使用改良型髋部保护器的依从率

梁国穗，施品正，张颖恺，谭锦辉，吴伟坚，朱琏碧

香港中文大学骨科

目的：髋部保护器(hip protector, HP)是预防髋部骨折的有效方法，其主要的缺陷在于依从性差，而穿着不舒适及不合身是依从性差的主要原因。本研究对改良型HP的力衰减特性以及其

在香港居家老年人中使用的依从性进行了研究。

方法： 本研究采用了一种改良型 HP，其体积较西方的设计小 50%，同时加入了硅填充材料以增加舒适性，并按照香港本地人的人体测量数据进行设计。利用自高处坠落的重物来撞击放了 HP 和没有放 HP 的应力板，以此模拟摔倒时 HP 的受力情况，并检测其力衰减特性(Kistler 9285)。来自四个老年中心(OAH)的 180 名 70 岁以上的老年步行女性参与了本研究，OAH 的员工在为期一年的研究过程中，采用不公开的检查方法，按照研究计划记录了 HP 使用的依从率。

结果： 在摔倒模拟实验中，使用 HP 后的冲击力显著降低($p<.001$)，并且明显低于造成老年女性股骨近端骨折所需冲击力的阈值(3100N, $p<0.001$)。在前 6 个月中，64%的受试者愿意穿着 HP，平均依从率为 55.8%(夜间 55.4%，白天 56.2%)。受试者不愿穿着 HP 的主要原因是由于笨拙感和闷热感。在高依从率组(平均依从率>70%)，有骨折史及反复摔倒史的受试者居多，但没有显著差异。

总结： 实验研究证实 HP 是一种有效的预防骨折的方法。然而，尽管在传统设计的基础上经过数次改进，HP 仍然无法在临床试验研究中在依从性方面有重大突破。 新型的气囊 HP 也许可以更好地解决依从性问题。

感谢： 华永会，余兆麒医疗基金

Compliance Rate of a Modified Hip Protector Among Old Age Home Residents in Hong Kong

Leung KS, Sze PC, Cheung WH, Tam KF, Ng WK, Chu LP

Department of Othopaedics and Traumatology　The Chinese University of Hong Kong, HKSAR

Objective: Poor compliance is the major obstacle for hip protector (HP) to be an effective approach to prevent hip fractures. Un-comfort and poor fitting are the major reason of non-compliance. This study evaluated the force attenuation properties of a modified HP and its compliance among old age home residents in Hong Kong.

Method: A modified design HP was developed with 50% smaller in size when compare to western designs. Silicon padding was also added to improve comfort. Anthropometric consideration was made to fit the body figure of the local population. Force attenuation property of the HP was tested by dropping a weight from a height which simulates the physical condition of fall to a force plate (Kistler 9285) with and without placing the HP. One hundred and eighty ambulant female residents with age 70 or above were recruited from four local old age homes (OAH) for this compliance study of the modified HP. Compliance rate was recorded by OAH staff in unannounced checks as scheduled by the investigators for a one-year period.

Results: The impact force in fall simulation study was significantly lower ($p<.001$) with the application of HP, and was found to be significantly lower than the fracture threshold of proximal femur of old ladies (3100N, $p<0.001$). There were

64% of subjects accepted to wear HP with average compliance rate 55.8% (night 55.4%, day 56.2%) for the first six months. The major reasons for non-compliance were clumsiness and hotness. There were more subjects with fracture history and recurrent falls in the high compliance group (average compliance rate>70%) although the difference was not significant.

Conclusion: HP was found to be effective to prevent fracture in laboratory study. However, it is difficult to have breakthrough on compliance with the traditional design in clinical trials although several modifications have been made. Innovative design like airbag HP may be a better way to encounter the compliance problem.

Acknowledgments: BMCPC, SK Yee Medical Foundation

老年人群中的摔倒相关损伤：地区医院的3105例病例报告

林佩诗，林子平，施品正，吕宝仪，梁国穗

香港中文大学 威尔斯亲王医院骨科

介绍： 老年人摔倒相关损伤是医疗护理系统的沉重负担，其可有较高的发病率和死亡率。对于这些患者的研究可以帮助我们更好的理解、预防和处理这些老年人群中重要的健康问题。

方法： 对一所服务于60万人口的地区性医院的急诊科，在2002年内所接诊的60岁以上患者的医疗记录进行回顾性研究。

结果： 在5726创伤病例中，摔倒所造成的为3105例(54.2%)。每年每千人的男女发病人数分别为22.9 (95%CI: 21.56-24.31)和56.0 (95%CI: 53.77-58.24)。矫正性别因素后，在60岁以上每10年一个年龄段中，随着年龄增加，于急诊就诊的风险越高(IRR: 2.15)。矫正年龄因素后，女性患者的就诊风险为男性的两倍(IRR: 1.97)。24.8%为骨损伤。女性患者下肢(RR: 1.17)和脊柱损伤(RR: 1.51)的风险明显高于男性，而男性头、面部损伤的风险较高(RR分别为0.85和0.64) ($p<0.001$)。女性摔倒患者髋部骨折和腕部骨折明显高于正常(RR分别为1.62和1.56) ($p<0.05$)。

讨论和总结： 摔倒相关损伤是老年人群中一种严重的健康问题，女性及高龄患者更容易受累。这些，对于我们计划针对老年人群摔倒相关损伤的预防和处理措施，均有重要的参考意义。

Fall-Related Injuries in the Elderly Population : A Study of 3105 Cases Seen at a Regional Hospital

Lam PS, Lam TP, Sze PC, Lui PPY, Leung KS

Department of Orthopaedics and Traumatology

The Chinese University of Hong Kong

Prince of Wales Hospital, Hong Kong SAR

Introduction: Fall-related injury among the elderly is a heavy burden to the health care

system and can carry significant morbidity and mortality. A study of these patients will help us to better understand, prevent and manage these important health problems in the elderly population.

Methods: The medical records of all cases at or older than 60 years of age and with fall-related injuries seen in 2002 at the Accident and Emergency Department of a regional hospital serving a population of 0.6 million were retrospectively reviewed.

Results: Among 5726 trauma cases, 3105 were fallers (54.2%). The incidence rate for male and female were 22.9 (95%CI: 21.56-24.31) and 56.0 (95%CI: 53.77-58.24) per 1000 person-year respectively. Increasing age had increasing risk of A&E admission (IRR: 2.15) for every decade after 60 after adjustment for the effect of gender. Female had twice (IRR: 1.97) the risk of A&E admission after adjustment for the effect of age. 24.8% had hard tissue injury. Female had significantly higher risk of lower limb injury (RR: 1.17) and spinal injury (RR: 1.51) while male had significantly higher risk of head and face injury (RR: 0.85 & 0.64 respectively) ($p<0.001$). Hip fractures and wrist fractures were significantly more common among the female fallers (RR:1.62; 1.56 respectively) ($p<0.05$),

Discussion and Conclusion: Fall-related injury is a serious health problem among the elderly. Female and older age group are more susceptible. All these will be important references for planning preventive measures and management for this serious health issue in the elderly population.

关节镜下关节清理术和透明质酸钠治疗膝关节骨性关节炎

林晓生 林晓蓬 蔡道章

深圳市宝安区中医院(518133)

膝关节骨性关节炎是临床常见的中老年退行性骨关节疾病，主要累及滑膜关节。关节疼痛及活动受限是其主要临床表现，其病因和发病机制尚未明确，目前治疗方法有关节镜清理、止痛、理疗功能锻炼、粘弹样补充疗法、截骨矫正下肢力线、骨钻孔减压、人工膝关节置换等方法。自1998年10月~2003年9月对膝关节骨性关节炎患者采用关节镜下关节清理联合透明质酸钠注射治疗，获得2年以上随访96例（108膝），分析如下：

1 临床资料

1.1 一般资料

本组96例（108膝），其中男51例（59膝），女例45（49膝），年龄50~71岁，平均年龄60.2岁。发病部位：右膝38例，左膝46例，双膝12例。病程5个月~12年，平均16.8个月。本组

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Concurrent Free Papers 6: General/Trauma

6.1

Fall-related Injuries in the Elderly Population: a Study of 3105 Cases Seen at a Regional Hospital

Lam PS, Lam TP, Lui PPY, Leung KS

Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Prince of Wales Hospital, Hong Kong

Introduction: Fall-related injury among elderly people is a heavy burden to the health care system and can carry significant morbidity and mortality. A study of these patients will help us to better understand, prevent and manage these important health problems in the elderly population.

Methods: The medical records of all patients aged 60 years or older and with fall-related injuries seen in 2002 at the Accident and Emergency Department of a regional hospital serving a population of 0.6 million were retrospectively reviewed.

Results: Among 5726 patients sustaining trauma, 3105 were fallers (54.2%). The incidence rates for men and women were 22.9 (95% confidence interval, 21.56-24.31) and 56.0 (95% confidence interval, 53.77-58.24) per 1000 person-years, respectively. Increasing age was associated with an increasing risk of admission to the Accident and Emergency Department (IRR, 2.15) for every decade after 60 years, after adjustment for patients' sex. Women had twice the risk of admission to the Accident and Emergency Department than men (IRR, 1.97), after adjustment for age. Some 24.8% had hard-tissue injury. Women had a significantly higher risk of lower-limb injury (RR, 1.17) and spinal injury (RR: 1.51) than men, whereas men had a significantly higher risk of head (RR, 0.85) and face injury (RR, 0.64) than women ($p < 0.001$). Hip fractures (RR, 1.62) and wrist fractures (RR, 1.56) were significantly more common among the female fallers than male fallers ($p < 0.05$).

Discussion and Conclusion: Fall-related injury is a serious health problem among the elderly population. Females and older age groups are more susceptible than others. All these will be important references for planning preventive measures and management for this serious health issue in the elderly population.

6.2

Readmission Rate of Older People with a History of Fractures as a Result of Fall-related Injuries in Hong Kong

Sze PC,[1] Lam HY,[2] Leung KS,[1] Cheung WH,[1] Wong WK[1]

[1]*Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, and* [2]*Department of Orthopaedics and Traumatology, Alice Ho Miu Ling Nethersole Hospital, Hong Kong*

Introduction: Having a history of fracture is a risk factor for recurrent falls, and the consequence is potentially more serious. This study investigates the readmission rate as a result of fall and its consequence among older people with history of fractures in Hong Kong.

Methods: Patients aged 60 or older who were admitted to orthopaedic wards in the Prince of Wales Hospital and who had fractures diagnosed during between April 2001 and August 2002 were included in this retrospective study. Any Accident and Emergency Department readmission record of these patients within the following 12 months after discharge were collected and reviewed through the clinical management system of the Hospital Authority.

Results: There were 837 cases reviewed. The mean age of the patients was 79 years (SD, 8.8 years); 14.5% were men and 85.5% were women. Fifty one percent of the patients fractured their hip, whereas 49% fractured other body sites. The fall-related readmission rate for all patients was 9.2%; the rate was slightly higher among the hip fracture group (10.9%) than among the non-hip fracture group (7.5%). Half of the readmitted patients (hip fracture group, 31%; non-hip fracture group, 74.2%) had fractures as a result of a recurrent fall ($\chi^2 = 16.3$; $p < 0.001$).

Discussion and Conclusion: Both the fall-related readmission rate and the fracture rate among older people with a history of fracture are higher than those among the general elderly population (fall-related readmission rate, 2.3% to 5.6% for males and females; fracture rate, 24%). It is necessary to introduce secondary and tertiary fal- and fracture-prevention programmes in discharge programmes for patients with fracture.

6.3

The Second Hip Fracture: Retrospective Database Analysis of 850 Elderly Patients

Lai FHY,[1] Lam CY,[2] Law SW,[2] Wong EMC,[3] Soo AKW,[1] Chan CKC,[1] Tse PLC,[1] Yip KTF,[1] Wong SKM[1]
[1]Occupational Therapy Department, and [2]Department of Orthopaedic Rehabilitation, Tai Po Hospital, and [3]Centre of Epidemiology and Biostatistics, School of Public Health, The Chinese University of Hong Kong, Hong Kong

Introduction: Elderly patients tend to fall more often for various reasons. Clinically, there is a tendency that elderly patients sustain a second hip fracture.

Methods: A retrospective database on a group of geriatric patients who had a second hip fracture from 2001 to 2004 was epidemiologically reviewed. Data were collected in terms of general status of patients, comorbidities, fracture types, interval between the 2 fractures, types of operation, postfracture independence level, and potential in rehabilitation after second hip fractures.

Results: 850 patients (612 women and 238 men) were reviewed; 69 patients sustained second hip fractures. Patients' ages ranged from 65 to 88 years (mean, 75.6 years) and 72 to 92 years (mean, 81 years) for the first and second hip fracture, respectively. The interval between the operation ranged from 2 to 81 months (mean, 52 months; median, 30 months). A significant difference was noted in length of rehabilitation stay, FIM score, and FIM change efficiency between first and second hip fracture group ($p < 0.01$). The incidence of second hip fracture was 8.1%, which was higher than in a previously reported paper. Half of the second hip fractures occurred on the same side as the previous fracture. Twenty two patients had first a subcapital fracture following an intertrochanteric fracture. No patient had a subcapital fracture following an intertrochanteric fracture.

Discussion and Conclusion: Most patients with second hip fracture show poor potential in rehabilitation, and deteriorated functional condition when compared with the first hip fracture group. Subcapital fractures tend to appear at a younger age compared with intertrochanteric fractures.

6.4

Effectiveness of a 1-year Fall Prevention Community Model Programme in Hong Kong

Lam PS, Sze PC, Chan T, Leung KS
Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Hong Kong

Introduction: Falls are a common injury method among elderly people. Fall-related fracture of the femur is the fourth major cause of bed occupancy in public hospitals with 150,000 bed-days. A fall prevention community-based programme aimed at reducing the number of falls and fractures among elderly people in Hong Kong.

Methods: The fall prevention community-based programme was established in an elderly organisation in Hong Kong in 2003. A total of 188 elderly people participated in the fall risk screening. Community interventions were prescribed to different risk groups — for example, exercise classes, home assessments, home modifications, and fall prevention clinic visits for detailed medical and balance assessments. Each participant was prescribed a fall calendar to record fall incidences. Fall records were collected every month for 1 year. Balance and subjective confidence scale were assessed. Paired t tests were used to compare the differences in fall incidences, balance, and subjective confidence scale scores before and after the 1-year intervention.

Results: 116 elderly participants finished the 1-year programme. The fall incidences significantly dropped from 0.97 to 0.31 ($p < 0.001$). Among the 63 fall prevention clinic attendants, balance showed significant improvements in Berg balance scale scores ($p = 0.0033$), backward directional control ($p = 0.002$), and voluntary backward degree of movement ($p = 0.04$). Activities-specific balance confidence scale scores showed significant improvement in daily activities ($p = 0.0036$).

Discussion and Conclusion: The 1-year community fall prevention programme showed promising results in reducing the number of falls and in improving balance. The ultimate goal of reducing the number of fractures can be achieved. Therefore, this community programme is successful and adaptable in the Chinese community.

6.5

Compliance Rate of Hip Protector among Old-age Home Residents in Hong Kong

Sze PC, Leung KS, Cheung WH, Lui PY, Chu LP
Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Hong Kong

Introduction: The efficacy of a hip protector in the prevention of hip fractures has been widely proved. However, poor compliance is the major obstacle to its use as an effective strategy. The objectives of this study were to evaluate the compliance rate of a modified hip protector among local people.

Methods: The modified hip protector was 50% smaller in size when compared with western designs. Silicon padding was provided to improve comfort. Anthropometric consideration was made to fit the body figure of the local population. 180 ambulant female residents aged 70 or older were recruited from 4 local old-age homes for this compliance study. The compliance rate was recorded by old-age home staff in unannounced checks, as scheduled by the investigators for a 1-year period.

Results: Sixty four percent of participants agreed to wear a hip protector with a mean compliance rate of 55.8% (night, 55.4%; day, 56.2%) for the first 6 months. The major reasons for non-compliance were clumsiness and hotness. There were more participants with a history of fracture and recurrent falls in the high-compliance group (mean compliance rate >70%), although the difference was not significant.

Discussion and Conclusion: The compliance rate of this study was comparable to that in other similar studies. Only a few characteristics of the participants were weakly associated with the compliance rate. Although several modifications have been made to the hip protector, more measures such as education, encouragement from family members, and exploration of new designs (e.g., airbag hip protector) should be taken to increase the compliance rate.

6.6

Simultaneous Hip and Upper Limb Fractures in Geriatric Patients: the Rehabilitation Consideration

Lai FHY,[1] Lam CY,[2] Law SW,[2] Wong EMC,[3] Soo AKW,[1] Chan CKC,[1] Tse PLC,[1] Yip KTF,[1] Wong SKM[1]
[1]Occupational Therapy Department, and [2]Department of Orthopaedic Rehabilitation, Tai Po Hospital, and [3]Centre of Epidemiology and Biostatistics, School of Public Health, The Chinese University of Hong Kong, Hong Kong

Introduction: There have been many studies on the epidemiology of hip fractures in the elderly population. However, there has been no documented analysis on the incidence or features of patients presenting with combined hip and upper limb fractures.

Methods: A retrospective database analysis was conducted on geriatric patients admitted to a rehabilitation hospital during 3 years with either trochanteric fractures or those of the neck of the femur.

Results: 850 patients were reviewed; 38 (4.5%) were found to have a fracture of upper limb. The associated upper-limb fractures were distal radius fractures (n = 12), neck of the humerus fractures (n = 15), and metacarpal fractures (n = 11). The female to male ratio in the isolated hip fracture group was 3.2:1 and for the combined fractures group, it was 8:1 ($p = 0.013$). The mean patient age was 78.2 years for isolated hip fractures and 84.9 years for the combined group ($p = 0.013$). The mean total length of rehabilitation stay for isolated hip fracture was 22.3 days and for combined fractures, it was 32.5 days ($p = 0.013$). A significant difference was noted in the length of rehabilitation stay, Functional Independence Measure change and its efficiency between the combined fracture group and the isolated hip fracture group ($p < 0.01$). Results indicated that combined upper limb and hip fracture occurs in a population that is older and predominantly female. There was a significant increase in hospital stay and deteriorated function as a consequence of combined fractures.

Discussion and Conclusion: Rehabilitation to this specific group of patients should include early stable fixation, immediate coordinated multidisciplinary team involvement, and rehabilitation.

International Society for Fracture Repair

ISFR SYMPOSIUM

International Symposium on Preventing Falls and Fractures in Older Persons

Yokohama, Japan
June 29 —July 1, 2004
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Program & Abstracts

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2-F1 A Study of the Epidemiology of Falls in Hong Kong

Chan T Jessica, Lam PS Helen, Sze PC Patrick, Leung KS

Department of Orthopaedics and Traumatology
The Chinese University of Hong Kong, China

The study of the epidemiology of falls and fall characteristics are important for the planning of fall prevention educational program in the community. In 2003, 1800 fall questionnaires were distributed to the attendants after our community fall prevention talks. Among the respondents, 51.8% of them (84.8% female, 15.2% male with mean age: 74.6) had fall experiences before while 16.8% responded that they had falls in the past year. 33.3% got mild contusion followed by fractures (22%). Wrist (37.4%) and hip (18.2%) were the commonest fractures sites. 61.1% of them fell in street, mostly due to tripping by obstacles, slipping and poor balance.

The elderly traumatic cases in 2002 (aged 65 or above) from Accident and Emergency department in Prince of Wales Hospital were collected. 52 % (n = 3100) traumatic cases fell into the fall category. Of these fallers, 24.3% got fractures, in which 36.6 % had hip fractures, followed by wrist fractures (28.4%). For the fall mechanism, 25.4% fell on buttocks, and 13.9% had sidefalls. Hypertension (31.2%), Diabetes Mellitus (15.2%), and heart diseases (10.3%) were the commonest associated medical diseases.

Besides, elderly who aged 65 or above and admitted to orthopaedic wards for treatments after falls were interviewed. 837 fall questionnaires were collected in the period of 2001-2002. Among the interviewees (87.6% female; 12.4% male), 43.7% fell at homes. Similarly, the two commonest fall mechanism were falling on buttocks (37%) and sidefalls (33%). The falls were mostly due to general weakness (19.5%), loss of balance (14.3%), tripping by obstacles (13.9%) and slipping (13.2%).

These findings helped us to design tailor-made fall prevention program to elderly in the community. They are also critical for the evaluation of the fall prevention programs in the community.

Acknowledgement: SK Yee Medical Foundation, Asian Association of Dynamic Osteosynthesis Community Service Fund

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- Mobility 54

3-F1 In Search of a Simplified Fall Risk Assessment for Chinese Elderly

Sze PC, Lam PS, Chan T J, Leung KS

Department of Orthopaedics and Traumatology
Prince of Wales Hospital, The Chinese University of Hong Kong, China

Introduction: Development of simple and accurate fall risk assessments to identify the risk of fall is critical in fall prevention programmes. This study investigated the validity of a simplified fall risk assessment for Chinese by comparing its results with that of a validated comprehensive Physiological Profile Assessment (PPA) developed by the Prince of Wales Medical Research Institute of Australia.

Method: 188 community-dwelling elderly aged 60 or above were selected by convenience sampling from community centres. All the subjects were asked for their history of fall in the previous 6 months. They were then assessed by a physiotherapist using PPA and the simplified test, which included the evaluation of fall and medical history, reaction, muscle power and balance. The score of each item was aggregated to generate a total score ranging from 0 to 12, with higher the score, higher the risk.

Results: The mean age of the subject was 74.61 (SD6.98). 15% of the subjects were multiple fallers while 85% of them fell either once or had no history of fall. The sensitivity and specificity for identifying these two groups by PPA were 0.607 and 0.597 respectively, while that of the simplified test yields the best combination at cut off point of 4, with values 0.5 and 0.538 respectively.

Discussion and Conclusion: The PPA may not be a good assessment for Chinese Elderly since the risk profile may be different across different culture and lifestyles. Although the specificity and sensitivity of the simplified test is relatively low, it represents one step towards a better assessment of Chinese population and high potential for clinical practicality. Further research is needed to improve the accuracy of the test.

Acknowledgement: Asian Association of Dynamic Osteosynthesis, SK Yee Medical Foundation, The Board of Management of the Chinese Permanent Cemeteries.

Sensitivity & Specificity ⇒ not a g. indicator for screening test.

4-F2 Effectiveness of a Community-based Model of Fall Prevention Program in Hong Kong

Lam PS Helen, Chan Jessica, Sze PC Patrick, Leung KS

Department of Orthopaedics and Traumatology
The Chinese University of Hong Kong, China

A Community-based Fall Prevention Program has been established in one elderly service organization in Hong Kong since late of 2002. 50 volunteers were recruited and trained to be "fall prevention trainers" assisting the running of fall prevention program in the community centres. All elderly subjects need to attend bimonthly fall prevention interest group meetings for fall prevention educational talks and regular updates of fall records with fall calendar prescription. Home visits to all subjects with appropriate advice on environmental hazards and home modification have been carried out by a physiotherapist and trainers 4 times a year.

200 community-dwellers were firstly categorized into low, moderate, or high risk groups after fall risk assessment. Subjects of low risks receive educational materials for self-reminders, while those of moderate risks need to join a fall prevention exercise class in community centre. Subjects of high risk are referred to fall prevention clinic for comprehensive medical and physical consultation, detailed balance assessment with Smart Equi test and exercise training. Multidisciplinary collaboration among medical professionals, social workers, volunteers closely monitor the fall incidence, home visit record, exercise attendance, and balance performance.

The interim results show significant improvement of the elderly in balance performance, and awareness of fall prevention in daily activities. Those attending balance training showed significant improvement in voluntary motor control, functional balance test ($p=0.002$), and self confidence towards daily activities ($p=0.0033$), and some improvement in sensory organization. For the continuous assessment of fall calendar, there have been 9.8% participants experiencing falls (2 participants having Parkinson's disease were frequent fallers) in the past 9 months compared with 29.3 % in the past year before joining this program. The average compliance of elderly in joining the interest group meetings, and exercise classes was about 70%.

Acknowledgement: SK Yee Medical Foundation, BMCPC, AADO community service fund.

4-F3 Medical Bal Persons

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Introduction
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3.5

Development of a Simple Fall Risk Screening Test for Chinese Community Elderly

Sze PC, Law SW, Lam PS, Chan T, Leung KS
Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Hong Kong.

Introduction: Fall risk assessments are critical in fall prevention programmes. However, current assessment tools mostly focus on in-patient and institution practice. This study investigated the validity and accuracy of a new fall risk screening tool for community elderly, whom account for the majority of the fall-related injuries.

Methods: One-hundred and eighty-eight community-dwelling elderly were selected from community centers and were assessed with the Physiological Profile Assessment (PPA) and the new screening test. The new screening test consisted of 4 items including fall and medical histories, response time, muscle power and balance, which summed to a score ranged from 0 to 12. Validity of the new screening test was assessed retrospectively by its ability to identify multiple fallers and comparison of the results with PPA.

Results: The mean age of the subjects was 74.61 (+/- 6.98). Fifteen percent of the subjects were multiple fallers while 85% of them fell either once or had no history of fall. The screening test yielded the best combination of sensitivity and specificity at cut off point of 4 (≤ 4 indicates low risk), with values 0.5 and 0.538 respectively. The stratified correlation of the two tests approached significance ($p = 0.059$).

Discussion and Conclusion: The screening test yielded satisfactory content and criterion-related validity. Furthermore, it is short and easy to administer, which makes it a tool with high practicality in the community. Further prospective study is recommended for further validation of the test.

Acknowledgement: Asian Association of Dynamic Osteosynthesis, The Board of Management of the Chinese Permanent Cemeteries.

3.6

An In-Vitro Mechanical Study of a Newly-Designed Hip Protector for Chinese Elderly

Sze PC, Lam PS, Chan T, Leung KS
Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Hong Kong.

Introduction: The major problem of current hip protector (HP) is that it makes the user uncomfortable and hence affects their compliance. A new HP made of thermoplastic covered with silicon cushioning layer for comfort and smaller size for cosmetic purposes may have potential to improve compliance. But before any clinical trials, an in-vitro study on its force attenuation property will be essential.

Methods: During the mechanical test, the HP was placed on a force plate (Kistler 9285) with the convex side facing upwards. A 3 kg metal ball was then dropped onto the HP by free falling. The dropping heights were adjusted so that the impact forces mimic the level of a low impact fall with muscle relaxation and a high impact fall with muscle contraction. The impact forces was recorded and compared to that without the HP.

Results: The mean impact forces for high and low impact were 10240 N (+/- 139 N) and 7330 N (+/- 366 N) respectively while our HP greatly reduced them to 724 N (+/- 96 N) and 465 N (+/- 39 N) respectively ($p < 0.001$). They were both found to be significantly lower than the fracture threshold of proximal femur of old ladies (3100 N, $p < 0.001$). The mean impact time also increased from 4 ms (+/- 0.5 ms) to 51 ms (+/- 3.9 ms) for high impact and from 4 ms (+/- 0.4 ms) to 31 ms (+/- 2.2 ms) for low impact with the HP ($p < 0.001$).

Discussion and Conclusion: This in-vitro study has proven the effectiveness of the newly-designed HP to protect the elderly hip from fractures mechanically. Further clinical trials would be done to investigate the compliance and efficacy of it.

Acknowledgement: AADO, SK Yee Medical Foundation, BMCPC.

3.3

Effectiveness of a Community-Based Model of Fall Prevention Program in Hong Kong

Lam PS, Chan J, Sze PC, Leung KS
Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Hong Kong.

Introduction: A Community-based Fall Prevention Program model aimed at integrating fall prevention knowledge into elderly's lifestyle and reducing fall and fracture incidences. Program was started by training fifty volunteers to be "fall prevention trainers" to assist fall prevention program in the community centers, including exercise classes, educational talks, home visits and fall calendar follow-ups. Effectiveness of Train-the-Trainers model and fall prevention clinic was assessed.

Methods: In 2003, two hundred community-dwellers were categorized into different risk groups (high, moderate, low) after fall risk assessments. Fifty-six subjects of high risks were referred to fall prevention clinic for comprehensive medical evaluation and exercise training. All participants were trained and monitored by trainers with staff supervision. Fall and fracture incidence, balance performance, and home hazards, were assessed for all groups by fall calendars, SmartEqui tests, functional balance tests and physiotherapists' home assessment respectively.

Results: Among high-risk participants, significant improvement was found in voluntary motor control, functional balance test ($p = 0.002$), and self-confidence towards daily activities ($p = 0.0033$). For fall records for all groups of subjects, 5.7% participants experienced falls in the intervention period compared with 39.5 % in the year before intervention.

Discussion and Conclusion: Effectiveness of community-based program will be analyzed at the end of program and 1-year follow-up. Fall prevention clinic was shown to be effective in balance improvement. A positive trend of fall reduction was seen in this period.

Acknowledgement: SK Yee Medical Foundation, Board of Management of the Chinese Permanent Cementeries, Asian Association of Dynamic Osteosynthesis Community Service Fund.

3.4

A Study of the Epidemiology of Falls in Hong Kong

Lam PS, Chan J, Sze PC, Leung KS
Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong, Hong Kong.

Introduction: Epidemiology of falls was important for planning of fall prevention program in the community. It was also critical for program evaluation.

Methods:

1) Community survey: 1800 fall questionnaires were distributed to the attendants after fall prevention talks in 2003.
2) Accident and Emergency Department (A & E) survey: 6244 elderly fall cases (aged 65 or above) were screened from A & E in Prince of Wales Hospital in 2002.
3) Orthopaedics wards survey: 837 orthopaedic inpatients (65 or above) after falls were interviewed in 2001-2002.

Results: Among talk respondents, 51.8% had fall experiences. 34% got mild contusion followed by fractures (23%). Wrist (39%) and hip (18%) were the commonest fractures sites. 61.1% fell in street, due to tripping by obstacles, slipping and poor balance. For elderly admitted to A & E, 24% got fractures, in which 36.6 % had hip fractures, followed by wrist fractures (28.4%). Among ward interviewees, 43.7% fell at homes. Falls were mostly due to general weakness (19.5%), and loss of balance (14.3%). There were common findings that most patients fell on buttocks, followed by sidefalls. Hypertension, diabetes and heart diseases were common comorbid conditions.

Discussions and Conclusion: Based on epidemiological findings, home represented an important environmental hazard to falls e.g. slippery floor or obstructed walkways but can be corrected by home modification. Physical deficit can be improved by balance training. Protection to the buttocks and hip may reduce the injury during falls.

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11.5

Vascular Endothelial Cell Growth Factor Incorporated Hydrogel Enhances Vascularization in Posterior Spinal Fusion Model

Cheng JCY,[1] Yeung HY,[1] Guo X,[2] Chiu YM,[1] Lee KM,[1] Chow PY,[3] Tabata Y[4]

[1]Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong; [2]Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Hong Kong; [3]Department of Anatomy, The Chinese University of Hong Kong; Hong Kong; [4]Institute for Frontier Medical Science, Kyoto University, Japan.

Introduction: In posterior spinal fusion, proper source of cells responsible for osteogenesis and good blood supply to the fusion site components are important for successful fusion. Decortication of osseous elements as a standard procedure is to provide osteoprogenitors and to initiate vascularization. In the present study, the angiogenic effect at fusion site by VEGF-incorporated hydrogel in posterior spinal fusion was investigated.

Methods: 12 New Zealand white rabbits underwent single level bilateral posterolateral spinal fusion. Three groups of animals with different dosages(0μg[control], 20μg, 40μg) of VEGF incorporated to the hydrogel were studied at week 3 and 7 post-operation. At week 3 post-implantation, immunohistochemistry of endothelial cell surface marker CD31 was preformed to quantify the endothelial cells and blood vessel density by image analysis system. By week 7 post-implantation, the fusion site was analyzed by micro-computed tomography.

Results: At week 3 post-operation, the number of endothelial cells in the hydrogel was significantly increased in a dose dependent manner. The blood vessels density at the hydrogel was also increased significantly at the experimental groups. For long-term (week 7 post-operation) effect of the enhanced vascularization in the system, the bone volume of transverse process of VEGF groups was reduced compared with control group. However, no significant difference in bone volume was demonstrated in the study.

Discussion and Conclusion: VEGF can be delivered effectively by hydrogel in posterior spinal fusion model for the enhancement of vascularization of fusion site. However, osteogenic effect of the VEGF is not demonstrated in the present study.

11.6

Fall Prevention Program — How it Sustains in the Community

Leung KS, Sze PC, Lam PS, Chan T

Department of Orthopaedics and Traumatology, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong.

The effect of fall prevention program is well documented in many studies. However, such effect diminished gradually in the community when the projects ended. The way to sustain such effect remained uninvestigated. This report describes methods to sustain such effect in the community.

We believe that the contribution and empowerment of community is an important factor for sustaining the effect through smooth liaison and proper training. Apart from talks in the community centre, we organise training courses for the senior volunteers to deliver the message of fall prevention in their community. Their service were organized and monitored by the staff from individual centre who completed our staff training course and qualified objectively both on knowledge and skill on running fall prevention programs. These programs would be further incorporated into the regular programs of the community centers to make it sustains with continual consultancy and monitoring by us through regular meetings with them.

Since April 2001, 202 senior volunteers had been trained and they had contributed in over 200 fall prevention programs which were organized by the community centers. There was 94% of the staff members found our training workshop useful for running programs in the community and express the willingness and confidence in running such programs continually. Further study is being done to investigate the effect of this approach on reducing the occurrence of fall in the community.

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