

NEWS

Hip, Hip Protectors, Hooray?

A recent study gives no cheers for one particular device, but experts remain optimistic in hip protectors as a promising intervention to prevent fractures

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Wearing an external hip protector that diverts or absorbs the energy of a fall away from the bone appears, at first glance, as a sensible and simple way to prevent the elderly from breaking their hips during falls. Yet, considering results from recent studies, it would be difficult to blame hip protector researchers from wanting to experience a break themselves - a break from a string of bad news and negative findings. Indeed, the most recent systematic review of clinical trials of hip protectors concluded that the devices are ineffective or of uncertain effectiveness. Meanwhile, the latest clinical trial, a well-designed study by Douglas Kiel, Stanley Birge and colleagues that experts agree overcame many of the flaws characteristic of previous trials, found that the protector it tested failed to prevent fractures. In fact, investigators were forced to shut the study down 2 years earlier than originally planned since an analysis revealed they would be unable to show any benefit to those wearing the protector, even if the study ran to completion.

"Initially there was a great deal of enthusiasm about hip protectors, and now there is increasing caution as each year goes by," says Ian Cameron, a professor of rehabilitation medicine at the University of Sydney who is now conducting clinical trials of the devices in Australia. Yet, despite the recent trend, most top researchers are actually quite optimistic for the future of hip protectors. In fact, they are worried about how the public might interpret recent negative findings. "I am concerned about whether these studies send the right public health message," says Stephen Robinovitch, a biomedical engineer with

expertise in the biomechanics of hip protectors. "The risk is that the public will hear this message and be turned off from the idea of hip protectors, as may manufacturers of the devices, and what I think is a really promising intervention will just fade into the woodwork, which would be wrong," says Dr. Robinovitch, also an associate professor in the School of Kinesiology and School of Engineering Science at Simon Fraser University in British Columbia.

As a sign that recent results are anything but a coup de grâce to the field, Dr. Robinovitch has organized a group, which includes Dr. Cameron, Dr. Kiel, and Dr. Birge, along with other experts from a range of disciplines, called the International Hip Protector Research Group. Initially funded by the Canadian Institutes of Health Research, the group, which will meet for the first time in November, aims to ensure that the promise of hip protectors can eventually be realized. What explains this continued effort and focus - this optimism - in the face of such recent unfavorable outcomes?

It turns out that recent results are less of an indictment of hip protectors as a class of devices, and more of a condemnation of specific individual hip protectors and the way in which they have been designed and biomechanically tested, and the manner in which clinical trials have been constructed to gauge their efficacy. "The field itself is a jungle," says Jonathan Howland, a professor of social and behavioral sciences at the Boston University School of Public Health and also a member of the research group. "There is no consensus about what a hip

protector is, there are no standards regarding the biomechanical properties that a hip protector should possess, and there is no consensus about how hip protector trials should be conducted and how the variables within those trials should be operationalized," Dr. Howland says. Far from being a simple matter, designing hip protectors, along with clinical studies to prove their value, is an endeavor that has been bedeviled by stubborn issues whose solution will require expertise in biomedical engineering, clinical trial design, behavioral science, education, and fashion. However, if these issues can be adequately addressed, the current jungle may be cleared, and hip protectors could have a bright future in the bone field.

Initial Promise, Subsequent Confusion, and the Latest Setback

The first clinical trial of hip protectors was conducted by Jes Lauritzen and colleagues in 1993. This initial study jumpstarted the field, and numerous clinical trials of hip protectors have since been conducted outside of the United States in Europe, Asia and other regions, with two basic designs. In the first, called cluster randomization, a group, such as the residents of a nursing home, was randomized to treatment with a hip protector, while a group of residents at another nursing home was randomized to receive no treatment. Metaanalyses of all of these types of studies revealed a significant reduction in hip fractures with the use of hip protectors. In contrast, in the second design, individuals were randomized to treatment or no treatment. Confusingly, metaanalyses of all of those types of studies found no benefit in fracture risk reduction to those wearing the devices.

"This was a strange situation where one study design showed that hip protectors worked, while another study design showed that they didn't work," says Douglas Kiel, lead author of the most recent clinical trial, published in *JAMA* in July (1). "In fact, the exact same hip protector could be found effective or ineffective, depending on the study design," says Dr. Kiel, director of medical research at the Institute for Aging

Research at Hebrew SeniorLife in Boston and also an associate professor of medicine at Harvard Medical School. Consequently, Dr. Kiel hypothesized that flaws in study design, rather than flaws in the hip protectors themselves, were responsible for such conflicting findings. For instance, in a cluster randomized trial, if the nursing staff at a nursing home randomized to treatment knew residents were receiving treatment, perhaps this affected the care they gave to them.

To overcome such potential biases, Dr. Kiel and his colleagues outfitted residents in US nursing homes with a hip protector worn on either the right or left hip, and compared hip fracture rates between the protected and unprotected sides. Since, in this type of design, each individual serves as his or her own control, some of the biases present in cluster randomized trials could be avoided. Unfortunately, even with this improved design, the study found that the hip protector, made of a dense foam and a thin, hard plastic piece embedded within the foam to provide structure, was not effective in preventing fractures. In fact, more fractures occurred on the protected side than on the unprotected side, though this finding did not reach statistical significance. Dr. Kiel and his co-authors concluded their study by writing that the "results add to the increasing body of evidence that hip protectors, as currently designed, are not effective for preventing hip fracture among nursing home residents."

Taking Out The Trash

Many experts not directly involved with the *JAMA* study have concluded that the particular device tested in the study was biomechanically ineffective, as have the study authors themselves. This does not surprise biomechanics experts like Dr. Robinovitch. "The protector tested in the *JAMA* study was only tested in one biomechanical study appearing in the literature by the person who invented it," he emphasizes. "There has never been any independent assessment of the biomechanical properties of this protector from a research group independent of the inventors of the protector." In fact, the field

has yet to agree on any biomechanical testing criteria that all hip protectors must meet in the laboratory before being tested in clinical trials. Currently, companies that sell hip protectors aren't even required to do any biomechanical testing. "There's absolutely no regulation of the industry at all," Dr. Kiel notes.

Considering this lack of standards and quality assurance, it is not surprising that many clinical trials have deemed the devices to be ineffective; garbage in, garbage out, as the computer scientists might say. One goal of the International Hip Protector Research Group is to ensure that less garbage gets in before the clinical trial process begins. To achieve this goal, hip protector development should begin with biomechanical testing in the laboratory, but that is only the start, according to Pekka Kannus, inventor of a hip protector called KPH. Dr. Kannus, also chief physician in the Injury and Osteoporosis Research Center at the UKK Institute for Health Promotion Research in Finland, points to KPH, reported in a 2000 *NEJM* randomized clinical trial to reduce fracture rates by 60-80% in a group randomized to hip protector treatment, compared to the no treatment group, to illustrate what he has in mind.

"We started from the very beginning – from baseline biomechanical testings in the laboratory – to find the best model that would theoretically reduce impact forces below the fracture threshold," Dr. Kannus explains. "We took those tests into account in the design of the protector, and then did a series of biomechanical tests in humans, followed by compliance studies in nursing homes, and then, finally, we did a randomized clinical trial." Because the KPH protector was tested in this fashion, Dr. Kannus believes that it is the basic solution for the field. "What is the type and model of hip protector that should function to reduce the impact forces below the fracture threshold? I still believe it's very near to our original KPH protector," says Dr. Kannus, also a member of the research group. However, without commonly agreed upon biomechanical testing standards, and in the absence of additional clinical trials repeated

by people not involved with a particular hip protector's creation, it is difficult to know for sure. "I haven't been convinced that there is a major difference in efficacy between available hip protectors," Dr. Cameron says.

Looks Do Matter

While many hip protector experts express similar views, there is nonetheless a good deal of optimism that biomechanically effective hip protectors can be designed because the scientific basis behind the devices, simple to understand, relies on straightforward engineering principles and laws of physics. As Dr. Robinovitch explains it, engineers consider a ratio called the factor of risk, where the numerator is the applied load – the force applied to the bone during a fall – and the denominator is the failure load – the force that, when applied to the bone, will cause a fracture. If, during a fall, this ratio is equal to or greater than 1, a fracture should ensue. While drugs like bisphosphonates aim to decrease this ratio by elevating the bone's failure load, hip protectors aim to decrease the ratio by lowering the applied load. "From the perspective of engineering and the laws of physics, there is really no reason to think that using hip protectors to prevent fractures is a flawed idea," Dr. Robinovitch concludes, based on this scientific logic.

Considering this scientific rationale, and assuming that universal standards can be developed for testing how well hip protectors reduce the force on the bone during a fall, researchers could be well on their way to developing a biomechanically effective hip protector. However, what is biomechanically effective is not necessarily something that elderly individuals will be willing to wear. Seemingly superficial matters like what looks good, and what is fashionable, are important; the engineers may build it, but the elderly, who still care about how they look, may not come.

To illustrate this intersection of science with appearance and fashion, and with market forces as well, consider the thickness of a hip protector. Dr. Robinovitch believes that a hip protector of about 2 inches thick is

necessary to provide adequate biomechanical protection. Yet the elderly may be unwilling to wear something that makes their hips look wider, and companies will be unlikely to spend resources developing products that potential customers won't buy. "The question is whether the market is willing to develop a thicker hip protector that will provide the required protection, but that will also require people to change their perception and attitude about what they are willing to wear," Dr. Robinovitch stresses.

What looks good is important, but what feels good may be even more crucial. Currently available hip protectors, which fit within a specially designed undergarment, are of two main kinds. The first is a hard, convex shell whose dome rises over the femoral trochanter and diverts the energy of a fall away from the bone and into the surrounding tissue. The second is a softer protector made primarily of foam that sits on top of the hip and absorbs the energy of a fall. Dr. Kiel questions the use of hard shell protectors on biomechanical grounds, noting that many elderly nursing home residents are frail and thin. "For the hard shells to work, the dome has to lie above the trochanter. If you are very thin, the dome of the convex shell may actually be touching the trochanter because there is no soft tissue to anchor it." Beyond biomechanics, though, hard protectors have another drawback: they are not very comfortable, and people don't tend to wear them. In fact, in data from an ongoing clinical trial, Dr. Cameron has found that, when given the choice between a soft hip protector or a hard one, $\frac{3}{4}$ of people choose the soft one because they perceive it as being more comfortable. "My impression is that as long as we have a technically effective soft protector, it will probably be better accepted by users," Dr. Cameron says. Interestingly, a recent cluster randomized study in Norway found that nursing home residents were about as likely to use soft protectors as hard ones during the day, but they were more likely to wear the soft ones 24 hours a day, including at night.

Randomized Clinical Trials To Demonstrate Hip Protector Effectiveness - Are They Even Necessary?

Designing hip protectors that look good and feel right is crucial because the field has been plagued by compliance issues. In fact, the inability of recent metaanalyses to determine whether clinical trials show no anti-fracture effect because hip protectors are biomechanically deficient, or because trial participants aren't wearing them, has led some experts to cast doubt on the conclusions of those metaanalyses. Furthermore, some experts point to, and are encouraged by, subgroup analyses in clinical trials showing that the better compliance is, the greater the reduction in relative risk for fracture.

Increasing compliance, though, entails much more than questions of fashion and comfort. For instance, is the nursing home staff convinced that hip protectors should be worn? Is the nursing home management committed to their use? Physicians will also need to be educated about hip protectors. "Most doctors don't even know that hip protectors exist," says Dr. Howland, who recently published a pilot study on physicians' knowledge of the devices. Clearly, only a wide range of expertise from numerous disciplines will increase hip protector use.

The challenge of poor compliance has led Robert Cumming, an epidemiologist who has worked with Dr. Cameron on clinical trials of hip protectors, to wonder whether the field really needs randomized trials to demonstrate that hip protectors prevent fractures. "The randomized trial is the paradigm for proving that medical interventions are effective, and that's perfectly reasonable," says Dr. Cumming, a professor of epidemiology and geriatric medicine at the University of Sydney. "However, there might be a small number of interventions, such as hip protectors, where perhaps the randomized trial isn't the right paradigm."

Indeed, some experts have compared hip protectors to the seat belt and to the bicycle

helmet, and, interestingly, Dr. Howland likens the current state of hip protectors to where the field of bike helmets was 25 years ago, before the advent of laboratory testing standards that have led to their widespread use. Neither seat belts nor bicycle helmets have been tested in randomized clinical trials to determine whether they prevent injuries. Yet, they have been proven to work in laboratory testing, as many crash dummies, if they could, would attest. Dr. Cumming believes that, in the case of hip protectors, laboratory demonstration of their biomechanical effectiveness will be sufficient to prove that they work. Therefore, clinical trials should focus instead on testing various methods for increasing compliance. Dr. Cameron is currently running just such a clinical trial right now, where compliance will be the primary outcome of the study.

Experts would welcome a solution to the compliance issue, and to the other problems that have beleaguered the hip protector field, considering that elderly people are at high risk for falling and could greatly benefit from an intervention that reduces the impact of a fall, particularly a non-pharmacological intervention. Notably, the *JAMA* study authors were taken to task by the Associated Press for failing to disclose to *JAMA* that they had received funding in the past from companies that sell osteoporosis drugs. Dr. Kiel says that the implication of the AP report – that he and his co-authors were trying to steer people towards drugs – was entirely opposite to their intent, since they believe that expensive, slow-acting

bisphosphonates with gastrointestinal side effects are often a poor option for very frail, elderly nursing home residents in need of more immediate remedies. (He also notes that their study did not even test drugs, further supporting their stance, with which *JAMA* has sided, that their company ties were not directly relevant to their study). Nevertheless, improving the biomechanical properties of hip protectors is not enough to reach this non-pharmacological goal. "Only a multifactorial intervention will be effective," says Dr. Lauritzen, director of the Department of Orthopedics and Internal Medicine at the University of Copenhagen Health Science Faculty and also part of the research group. "Solely focusing on hip protectors in and of themselves is an insufficient preventive program," he emphasizes, echoing the majority view that biomechanical remedies must be accompanied by educational and behavioral solutions that get the elderly to actually wear the devices. Solving the compliance conundrum will give hip protector researchers not only a real break from discouraging recent findings, but also a true breakthrough.

References

1. Kiel DP, Magaziner J, Zimmerman S, Ball L, Barton BA, Brown KM, Stone JP, Dewkett D, Birge SJ. Efficacy of a hip protector to prevent hip fracture in nursing home residents: the HIP PRO randomized controlled trial. *JAMA*. 2007 Jul 25;298(4):413-22.