

MATURITY HEALTH MATTERS

FDA Health News for Older Adults, Their Families and Caregivers

Issue 3

Summer 2006



Joint Replacement: An Inside Look

The American Academy of Orthopaedic Surgeons (AAOS) calls total hip replacement an orthopedic success story, "enabling hundreds of thousands of people to live fuller, more active lives." According to the National Center for Health Statistics, during 1995-2004, for people 65 years and older, the rate of hip replacements increased 38%, and the rate of knee replacement increased 70%.

Total knee replacement is "highly successful in relieving pain and restoring joint function," says the AAOS. A hip or knee replacement may last at least 20 years in about 80 percent of those who get them.

But despite their success, hip and knee joint replacements (also known as artificial joints) still have drawbacks. There may be complications. They don't always last a lifetime and when they fail, another surgery may be needed.

As artificial joints and implanting techniques to implant them continue to improve, the medical community and patients hope for joint replacements that cause fewer problems, last longer, and move more like a healthy natural joint.

What Is Joint Replacement?

Joints are formed where the ends of two or more bones come together. The bones are connected by ligaments and the ends of the bones are covered by another type of tissue called cartilage. Healthy cartilage serves as a protective cushion, allowing smooth, low-friction movement of the joint. If the cartilage becomes damaged by disease or injury, the tissues around the joint become inflamed and start to break down causing pain. With time, the cartilage wears away, allowing the rough edges of exposed bone to rub against each other, causing more pain. When joint pain cannot be helped by usual conservative measures such as pain medicine and exercises (physical therapy) or a person cannot perform daily activities, it may become necessary to surgically replace the joint.

When only some of the joint is damaged, a surgeon may be able to replace just the damaged parts. When the entire joint is damaged, a total joint replacement is done. To replace a total hip or knee joint, a surgeon removes the diseased or damaged parts and inserts artificial parts. Artificial joints are medical devices that must meet FDA's regulatory requirements before they can be marketed in the U.S.

Why Joint Replacement?

The most common reason for having a hip or knee replaced is osteoarthritis, according to the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). This gradually worsening degenerative joint disease, marked by the breakdown of the joint's cartilage, is not limited to older people. Although it most commonly affects people over age 45, younger men and women also can get this disease.

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Some people are born with a deformed joint or defective cartilage, which leads to osteoarthritis, a long-term disease that causes the cartilage between the bone joints to wear away, leading to pain and stiffness. Excess weight, joint fracture, ligament tears, or other injury can initiate damage to cartilage and lead to the development of osteoarthritis.

Rheumatoid arthritis, a long-term disease that causes inflammation of the soft tissues surrounding the joints, is another condition that may be improved by hip or knee joint replacement. The inflammation of the joint lining causes pain, stiffness, and swelling. The inflamed lining can invade and damage bone and cartilage. Rheumatoid arthritis generally starts in middle age, but some types can also affect children and young adults. Loss of bone caused by poor blood supply (osteonecrosis) and bone tumors may be other reasons for joint replacement.

What Is Hip Replacement Surgery?

The hip joint is a ball and socket, allowing a wide range of motion. The ball of the joint, at the top of the thighbone, moves within the hollow socket of the pelvis. A layer of cartilage on both sides allows the ball to glide smoothly inside the socket.

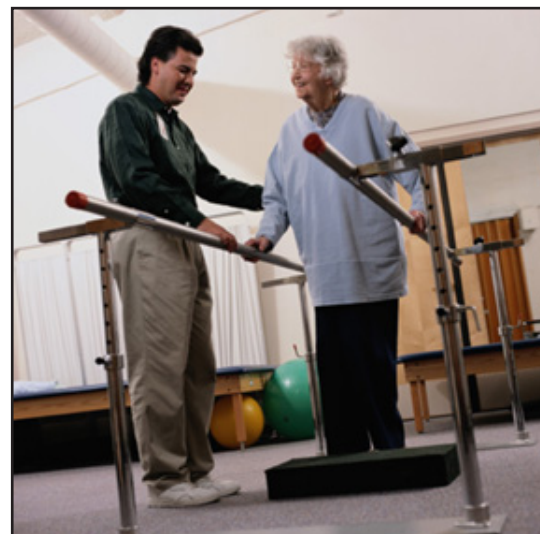
In total hip replacement, the surgeon cuts away the ball part of the joint and replaces it with a ball attached to a stem that is wedged into a hollowed-out space in the thighbone. Damaged cartilage and bone are removed from the socket and a cup-like part is inserted into the socket.

Hip replacements may be cemented or uncemented. If cemented, the hip parts are held in place with a fast-curing "bone cement" made from a synthetic compound. If uncemented, the joint components are specially made to either press into the bone for a tight fit or to allow new bone or soft connective tissue to grow into the porous surface coating on the implant, holding it in place.

What Is Hip Resurfacing?

An alternative option to a total hip replacement is total hip resurfacing. Unlike the artificial implant used in total hip replacement, which replaces the top of the thighbone, a total hip resurfacing implant design allows the ball part of the joint to be preserved and reshaped. The resurfaced ball-shaped bone is then capped with a short stemmed metal resurfacing implant. Like total hip replacement, the socket is fitted with a cup-like implant. The cap moves within the cup. The cap and cup surfaces that rub against each other are currently available only in highly-polished metal. Therefore, this implant is called a total metal-on-metal hip resurfacing device.

Not everyone is a candidate for total hip resurfacing. Patients who currently receive these devices may be relatively younger in age or have an increased activity level as compared to patients receiving traditional total hip replacement. In addition, patients must have bones that are strong and healthy enough to hold the resurfacing component. After joint replacement or revision surgery, tiny particles of metal may be released. So, it is important that kidneys be in good condition in order to filter these and other impurities out from the body. The surgeon will need complete information about a patient's overall health to determine whether the total hip resurfacing device is right for the patient. The doctor should be told about any health problems, even if it is not related to the hip, because some medicines as well as diseases (such as diabetes) can affect kidney function or bone strength in the future.



Joint Replacement - Continued from page 2**What Is Knee Replacement Surgery?**

The largest joint in the body, the knee joint, is formed where the lower part of the thighbone joins the upper part of the shinbone and the kneecap. Shock-absorbing cartilage covers the surfaces where these three bones touch.

In a standard total knee replacement, the damaged areas of the thighbone, shinbone and kneecap are removed and replaced with an artificial knee joint. The ends of the remaining bones are smoothed and reshaped to accommodate the implant. Pieces of the artificial knee joint are typically held in place with bone cement but some devices are for uncemented use. If uncemented, the joint components are specially made to allow new bone or soft connective tissue to grow into the porous surface coating on the implant, holding it in place.

Ninety percent of those who have total knee replacement report fast pain relief, improved movement, and better quality of life, according to independent experts. Studies have showed that revision surgery was needed in 10 percent of knee replacements after 10 years, and in 20 percent after 20 years, according to an FDA advisory panel.

What Is Revision Hip and Knee Surgery?

Revision surgery, which may replace both artificial parts and damaged bone, is more difficult than first-time surgery, says NIH's NIAMS. Because bone may not be as strong as when first operated on and the supporting tough band of tissue (ligaments) that serves to connect the bones may be damaged, revision surgery is more challenging and may lead to different or more complications.

What Are the Risks of Replacement Surgery?

Like any surgery, hip and knee joint replacement carries certain life-threatening risks, such as infection, blood clots, and complications from anesthesia or the use of bone cement. Other complications include nerve damage, dislocation of the implant, thigh bone fracture, or wearing out or loosening of the joint over time. After hip replacement surgery, one leg may be shorter than the other.

In the rare case that an infection spreads to the new joint and does not clear up with antibiotic treatment, the joint must be removed and replaced. This usually requires two surgeries--one to remove the infected joint and another surgery later to insert a new artificial joint. Between surgeries, the infection is treated with antibiotics.

What Is the Wear Problem?

The most commonly used joint implant for knees and hips are made of metal and plastic. The metal is usually a mixture of metals (an alloy). The plastic used in joint replacement is a specially processed polyethylene. Other materials manufacturers have produced to make hip implants include metal-on-metal, ceramic-on-plastic, and ceramic-on-ceramic surfaces.

Although these materials are smooth and intended to be wear-resistant, the daily rubbing of these surfaces against each other during normal movements can create tiny particles or fragments. After many years, these wear particles may damage the surrounding bone, loosen the implant, and require another (revision) knee or hip joint replacement.

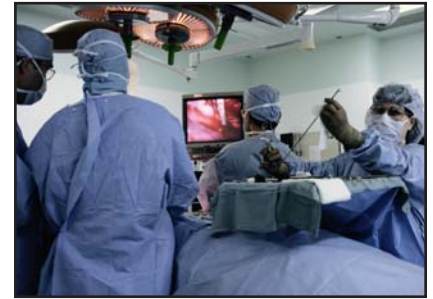
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When choosing an implant, the surgeon will consider many factors, including the patient's:

- age
- gender
- activity level
- general health
- weight
- anatomy
- medical history

The surgeon will also evaluate the medical device's performance record and his or her own experience with the medical device.



What Skills Must a Surgeon Have?

Choosing the appropriate implant is only one part of the decision for a successful hip or knee joint replacement. However, the most important part in a joint replacement success is the selection of a skilled surgeon who uses correct surgical technique. Always ask the surgeon, "How many implants have you done and what have been your complications?" You should consider the number of procedures performed by the surgeon at a hospital. Studies have found that surgeons and hospitals that have a low number of implant surgeries, on the average, have more complications than surgeons and hospitals with a high number of implant surgeries.

How Have Surgical Techniques Changed?

While implant makers are changing designs, materials, and manufacturing methods to try to lengthen the life of artificial knees and hips, surgeons are constantly refining techniques or developing new ones to try to improve the outcomes. Doing surgery through smaller incisions and performing less severe surgeries are among these efforts.

Some surgeons are performing these minimal-incision knee and hip replacement surgeries. Instead of the traditional 6- to 12-inch-long incision used in a standard total knee replacement, surgery is performed through a 4- to 5-inch incision. Instead of the typical 10- to 12-inch incision in a total hip replacement, surgeons are operating through one 4-inch cut or two 2-inch cuts.

Minimal-incision surgery is a more difficult operation to perform, and not all patients are candidates. People who are obese, have had previous hip or knee surgery, or those with unusual anatomy may be excluded.

Why Is Physical Therapy After Surgery Important?

After your surgery, a physical therapist will work with you to perform exercises which will serve to reduce pain and stiffness, strengthen your muscles, increase the range of motion and increase blood circulation as you return to your activities of daily living. It is important to regain the strength you may have lost before and after surgery before fully returning to your desired level of activity.

Additional Information

For more information about hip and knee replacements, visit:

National Library of Medicine's MedlinePlus:

- Hip Replacement: <http://www.nlm.nih.gov/medlineplus/hipreplacement.html>
- Knee Replacement: <http://www.nlm.nih.gov/medlineplus/kneereplacement.html>

Additional information from the American Academy of Orthopaedic Surgeons may be found by visiting: <http://aaos.org>

Source: FDA Consumer March-April 2004



Looking Through the Lens

Contact lenses are the number one choice for many people with vision correction needs. For many, contact lenses provide flexibility and convenience. If you want to wear contact lenses or renew your prescription, you must first see a licensed eye care professional. This is important because contact lenses are medical devices that must be prescribed and properly fitted. An eye care professional will ensure your eyes are healthy enough to wear contact lenses and that your contact lenses are working properly.

There are many different types of lenses available for a variety of needs and preferences. Contact lenses can be used to correct a variety of vision disorders such as nearsightedness, farsightedness, irregular curvature of the eye surface, and poor focusing with reading material and with other near vision tasks.

There are two general categories of contact lenses - soft and rigid gas permeable (RGP). In addition to the general categories of Soft and Rigid Gas Permeable, contact lenses can be further categorized as Daily Wear, Extended (or Overnight or Continuous) Wear, Disposable (Replacement schedule). These categories may overlap. For example, daily wear soft contact lenses may be prescribed on either a disposable or on a replacement schedule. It's important to remember that any contact lens must be cleaned and disinfected, or disposed of each time it's removed from your eye.

Soft Contact Lenses

Soft contact lenses are made of soft, flexible plastics that allow oxygen to pass through to the cornea. Soft contact lenses may be easier to adjust to and are more comfortable than rigid gas permeable lenses. Newer soft lens materials include silicone-hydrogels to provide more oxygen to your eye while you wear your lenses.

Rigid Gas Permeable (RGP) Contact Lenses

RGPs are more durable and resistant to deposit buildup and generally give a clearer, crisper vision. They tend to be less expensive over the life of the lens since they last longer than soft contact lenses. They are easier to handle and less likely to tear. However, they are not as comfortable initially as soft contacts and it may take a few weeks to get used to wearing RGPs. Although RGP lenses are usually worn on a daily wear basis, some are approved for extended wear.

Daily Wear

Daily wear contact lenses have been designed and FDA-approved to be worn only during waking hours (less than 24 hours). The majority of contact lens wearers use their lenses in this manner.

Extended wear

Extended wear contact lenses are available for overnight or continuous wear ranging from six nights up to 30 days. RGP lenses, are usually worn on a daily wear basis, but some are FDA-approved for extended

Eye Care Safety Tips - Do's

Here are some safety tips you should always follow if you wear contact lenses.

- Get regular eye exams.
- Have a back-up pair of glasses with a current prescription.
- Follow the directions of your eye care professional and labeling instructions.
- Wash your hands before handling lenses to help reduce the chance of an eye infection.
- Clean and disinfect your lenses properly.
- Clean, rinse and air-dry your lens case each time lenses are removed.
- Replace lens cases every three to six months.
- Remove the lenses immediately when your eyes become red, irritated, or your vision changes.
- Ask your eye care professional
 - about wearing glasses or contact lenses during sports activities.
 - about special instructions for lenses worn overnight.
 - before using any medicine or using topical eye products.
- Apply cosmetics after inserting lenses and remove lenses before removing makeup.
- Apply aerosol products (hairspray, cologne, and deodorant) before inserting lenses.
- Inform your employer if you wear contact lenses.
 - Jobs may require the use of eye protection equipment or require that you not wear contact lenses.
- Follow and save the directions that come with your lenses.
- Replace and discard your lenses as recommended by your eye care professional.

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Contact Lenses - Continued from page 5

wear. Length of continuous wear depends on lens type and your eye care professional's evaluation of your tolerance for overnight wear. Your eyes must rest without lenses for at least one night following each scheduled removal.

Disposable (Replacement Schedule)

The majority of soft contact lens wearers are prescribed some type of frequent replacement schedule. "Disposable," as defined by the FDA, means used once and discarded. With a true daily wear disposable schedule, a brand new pair of lenses is used each day.

Most soft contact lenses are replaced on a planned schedule, such as every two weeks, monthly, or quarterly. There is some confusion with this terminology, as some soft contact lenses may be referred to as "disposable" when they are actually prescribed for use on a planned replacement basis.

Risks

Wearing contact lenses puts you at risk of several serious conditions including eye infections and corneal ulcers. Corneal ulcers are open sores in the outer layer of the cornea. They are usually caused by infections.

Infections or corneal ulcers can develop very quickly and can be very serious, so never ignore any of the symptoms listed below. In rare cases, these conditions can cause blindness.

Symptoms of Eye Irritation or Infection

If you have one or more of the following symptoms, you may have an irritation or an infection.

- discomfort
- unusual sensitivity to light
- unusual redness
- swelling
- excess tearing or other discharge
- itching, burning, or gritty feelings
- blurred vision
- pain

If you experience any symptoms of eye irritation or infection:

- Remove your lenses immediately.
- Do not put the lenses back in your eyes.
- Contact your eye care professional right way.
- Keep your lenses in their case to take to your eye care professional for inspection.
- Report serious eye problems associated with your lenses to the FDA's MedWatch Reporting System at <http://www.fda.gov/medwatch/>.

For more information on buying contact lenses, FDA approved lenses, and other resource links, please visit FDA's contact lens website at <http://www.fda.gov/cdrh/contactlenses/>.

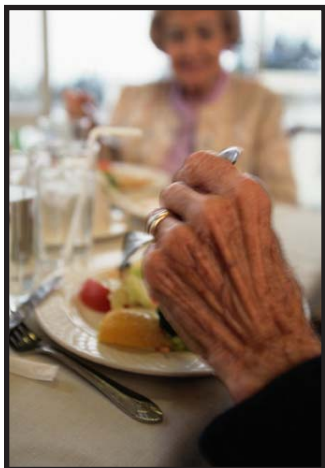
Source: <http://www.fda.gov/cdrh/contactlenses/>

Eye Care Safety Tips - Don'ts

Here are some safety tips you should always follow if you wear contact lenses.

Don't:

- sleep in daily wear lenses; they may promote your chance of infection or irritation
- purchase contact lenses from gas stations, video stores, record shops, or any other vendor not authorized by law to dispense contact lenses
- swap contact lens with another person
- smoke while wearing contact lenses; studies show that smokers who wear contact lenses have a higher rate of problems (adverse reactions) than nonsmokers
- swim while wearing contact lenses; pool bacteria may cause infection
- put your lenses in your mouth to wet them, saliva is not a sterile solution.
- use tap water, distilled water or any homemade salt solution to wet your lenses, tap and distilled water have been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure
- rely on contact lenses to protect your eyes from the sun, make sure to use sunglasses that block ultraviolet light
- reuse your contact lens disinfecting solution since it will dilute the chemicals that disinfect your lenses



Growing Older, Eating Better

Nutrition remains important throughout life. Many chronic diseases that develop late in life, such as osteoporosis, can be influenced by earlier poor habits. Not enough exercise and calcium, especially during adolescence and early adulthood, can significantly increase the risk of osteoporosis. Osteoporosis is a disease that causes bones to become brittle and crack or break easily.

But, good nutrition in the later years can also help lessen the effects of diseases common among older Americans or improve the quality of life in adults who have such diseases. These diseases include osteoporosis, obesity, high blood pressure, diabetes, heart disease, certain cancers, problems with the stomach and intestines (gastrointestinal), and chronic under-nutrition.

Studies show that a good diet in later years helps in reducing the risk of these diseases and in managing the diseases' signs and symptoms. Good diet contributes to a higher quality of life, shortens recovery time from illnesses, and enables older adults to maintain their ability to perform basic daily activities, such as bathing, dressing and eating.

The Single Life

Whether it happens at age 65 or 85, older adults eventually face one or more problems that interfere with their ability to eat well.

Social isolation is a common problem. Older adults who find themselves single after many years of living with another person may find it difficult to be alone, especially at mealtimes. They may become depressed, lose interest in preparing or eating regular meals, or they may eat very little.

In one study, researchers found that newly widowed adults, most of whom were women, were less likely to say they enjoy mealtimes, to have good appetites, and to report good eating behaviors. Thirty percent of older married couples had weight changes as compared to 85 percent of older adults during the two years after their spouse's death. The widowed group was more likely to report an average weight loss of 7.6 pounds.

A review of basic diet principles may help improve nutrition and prevent unnecessary weight loss. Explaining the importance of good nutrition to older adults in their later years may motivate them to make a greater effort to select nutritious foods.

Look to the Label

The food label can also help older adults select a good diet. The label gives the nutritional content of most foods and enables consumers to see how a food fits in with daily dietary recommendations.

Some of the information may appear as claims describing the food's nutritional benefits: for example, "low in cholesterol" or "high in vitamin C." Under strict government rules, these claims can be used only if the food meets certain criteria. This means that claims can be trusted. For example, a "low-cholesterol" food can provide no more than 20 milligrams of cholesterol and no more than 2 grams of saturated fat per serving.

Less common but also helpful are label claims linking a nutrient or food to the risk of a disease or health-related condition. These claims are supported by scientific evidence. One claim links whole grain foods to reduce the risk of heart disease and cancer. On the food label, this claim would read like this:

"Diets rich in whole grain foods and low in total fat, saturated fat, and cholesterol may reduce the risks of heart disease and some cancers."

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More in-depth information is found on the "Nutrition Facts" panel on the side or back of the food label. This information is required on almost all food packages and is now easier to read and understand. The food label is usually printed on a white or other neutral contrasting background.

Special Diets

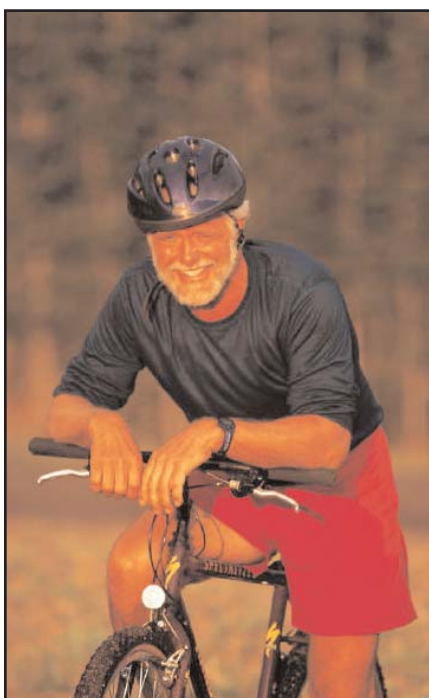
Many older adults, because of chronic medical problems, may require special diets: for example, a low-fat, low-cholesterol diet for heart disease, a low-sodium diet for high blood pressure, or a low-calorie diet for weight reduction. Special diets often require extra effort, but older adults may instead settle for foods that are quick and easy to prepare. They may choose frozen dinners, canned foods, lunch meats, and other foods that may provide too many calories or contain too much fat and sodium for their needs. Again, looking to the food label is one way to help make correct choices.

**Physical Problems**

Some older adults may overly restrict foods important to good health because of chewing difficulties and gastrointestinal disturbances, such as constipation, diarrhea and heartburn. Because missing teeth and poorly fitting dentures make it hard to chew, older adults may skip fresh fruits and vegetables, important sources of vitamins, minerals and fiber. They may avoid dairy products, believing they cause gas or constipation. By skipping nutritious foods, they miss out on important sources of calcium, protein and some vitamins.

Adverse reactions from medicines can cause older adults to avoid certain foods. Some medicines alter the senses and can adversely affect appetite, as well as the sense of taste and smell. These changes are also common as adults age.

Other medical problems, such as arthritis, stroke or Alzheimer's disease, can interfere with good nutrition. It may be difficult, for example, for older adults who have arthritis or who have had a stroke to cook, shop, or even lift a fork to eat. Dementia associated with Alzheimer's and other diseases may cause them to eat poorly or forget to eat altogether.

**Physical Activity**

Besides diet, physical activity is part of a healthy lifestyle at any age. It can help reduce and control weight by burning calories. Moderate exercise that places weight on bones, such as walking and light gardening, may help maintain and possibly even increase bone strength in older adults. Studies have shown that intensive strength training can help preserve bone density and improve muscle mass, strength and balance in postmenopausal women.

Regular exercise can improve the functioning of the heart and lungs, increase strength and flexibility, and contribute to a feeling of well-being. Before an exercise program is started or resumed after a long period of inactivity, talk to your healthcare provider.

Taking time out for exercise, using the food label to help pick nutritious foods, taking advantage of the several assistance programs available, and getting needed medical attention can go a long way toward helping older adults avoid the nutritional problems of aging and more fully enjoy their senior years.

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For More Information

For a more complete and simple guide to understanding and using the Nutrition Facts label, go to <http://www.cfsan.fda.gov/~dms/foodlab.html>.

To learn more about “eating healthy” in your later years, visit: To Your Health! Food Safety for Seniors, a joint venture between the FDA and the Department of Agriculture's Food Safety and Inspection Service <http://www.foodsafety.gov/~fsg/sr2.html> (updated November 2004)

To learn more about the food label, write for the publication Food Label Close-Up. Write to FDA, 5100 Paint Branch Parkway (HFS-555), College Park, MD 20740, and ask for publication number (FDA) 03-2283.

To read about FDA's Seniors and Food Safety- Preventing Foodborne Illness, go to <http://www.cfsan.fda.gov/~dms/seniors.html>

To find more resources for nutrition and a healthy lifestyle from the Administration on Aging, go to <http://www.aoa.gov/eldfam/eldfam.asp>.

Source: FDA Consumer: March 1996; Revised December 1996, June 2000, May 2001 and March 2003



FDA Approves New Treatment of Parkinson's Disease

The FDA recently approved Azilect (rasagiline) for the treatment of Parkinson's Disease (PD). The drug blocks the breakdown of dopamine, a chemical that sends information to the parts of the brain that control movement and coordination. Each year more than 50,000 Americans are diagnosed with PD.

PD is a long-term illness of the nervous system that becomes more severe over a period of time. This condition affects the nervous tissue adversely. It is caused by the destruction of the brain cells that produce dopamine. As the level of this chemical is reduced, messages from the brain telling the body how and when to move are delivered more slowly, leaving a person unable to start or control movements in a normal way.

Though full-blown Parkinson's can be crippling or disabling, experts say that in some people the symptoms of PD occur gradually. In others, the disease develops more quickly. Early symptoms of the disease may be so slight and gradual that patients sometimes ignore them or attribute them to the effects of aging. At first patients may feel overly tired or a little shaky. Their speech may become soft and they may become irritable for no reason. Movements may be stiff, unsteady, or unusually slow. As the symptoms worsen, patients may have difficulty walking, talking or completing other simple tasks. The disease usually affects people over 50 years of age and it progresses more quickly in some people.

The four main symptoms of PD are:

- Trembling of the hands, arms, legs, jaw, and face
- Stiffness of the limbs and body
- Slowness of movement
- Impaired balance and coordination

Other symptoms may include:

- Difficulty in swallowing, chewing and speaking
- Urinary problems or constipation
- Skin problems
- Sleep disturbances

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At present, there is no cure for PD, so Azilect is a welcome addition for the treatment of PD. Azilect was approved for use as an initial single drug therapy in early Parkinson's disease and as an addition to levodopa in more advanced patients. Levodopa is a standard treatment for PD.

Azilect users may experience dangerously high blood pressure if they also eat certain foods and beverages (such as cheese and red wine), dietary supplements, or certain cough or cold medicines. Therefore, patients will need to avoid these things while taking Azilect. As with most other medications for PD, people on Azilect may have uncontrolled movements, may see things that are not real (hallucinations), and may have lowered blood pressure. These side effects are described in the product labeling.

During development of the drug, skin cancer (melanoma) was diagnosed in a small number of patients treated with Azilect. The FDA has concluded that with the available data, Azilect is not associated with an increased risk for melanoma. However, it appears that compared to the general population, patients with Parkinson's disease have an increased risk for this form of skin cancer. In order to determine if Azilect increases such a risk, the drug's manufacturer will perform a study to follow patients who are using the drug. The product labeling recommends that patients have periodic exams by their skin doctor to check for melanoma.

For more information about Parkinson's disease, visit:

PD Information Page from NIH's National Institute of Neurological Disorders and Stroke
http://www.ninds.nih.gov/disorders/parkinsons_disease/parkinsons_disease.htm

PD Health Information Page from NIH's MedlinePlus <http://www.nlm.nih.gov/medlineplus/parkinsonsdisease.html>

Source: FDA News, May 17, 2006 <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01373.html>

Hurricanes: Health and Safety Before and After a Storm

The hurricane season is now upon us and it has been relatively quiet. But all it takes is one major storm to cause tremendous damage to one's health and home. When it comes to your health, do you know how to protect yourself before and after a hurricane? As a result of Hurricane Katrina, the FDA prepared a special website (<http://www.fda.gov/oc/opacom/hottopics/hurricane.html>) for consumers, specialized health care facilities, and restaurants. On this website, you will find information including:

- Medical Devices and Hurricane Disasters
- Medical Devices Exposed to High Heat and Humidity
- Disposal of Contaminated Devices
- Medical Devices Requiring Refrigeration
- Food Safety Advice for Consumers
- Home Food Safety After Hurricane, Flooding
- Safety of Potentially Damaged Medications by Flooding or High Temperatures
- Insect Repellent Use and Safety in Children
- Insulin Storage and Switching
- Biological Products in Severe Weather Conditions
- Other Information Sources and Public Service Announcements



FDA Approves a Second Drug for Prevention of Influenza A and B in Adults and Children

On March 29, 2006, FDA announced the approval of Relenza (for inhalation) for the *prevention* of flu in adults and children five years of age and older. Relenza, an antiviral medication, was previously approved only for the *treatment* of influenza A and B virus infections in adults and children. The approval of Relenza provides Americans with another option for the prevention of influenza A and B infections. Tamiflu, another antiviral drug previously was approved for both prevention and treatment of flu.

The effectiveness of Relenza in preventing seasonal flu has been shown in four large-scale studies comparing the drug with a drug with no effect (placebo). In two of these trials the use of the drug to a large extent, reduced the spread of flu in the participating households where participants were five years of age or greater. In both of these trials, the proportion of households that developed symptoms confirmed to be flu was 19.0% for the placebo group and 4.1% for the Relenza group.

In the other two trials, which were conducted in communities experiencing an influenza outbreak, Relenza reduced the incidence of the disease in both young and older populations. In the first study, with participants 18 years or older, the proportion of people who developed symptoms confirmed to be flu was 6.1% for the placebo group and 2.0% for the Relenza group. The second community study enrolled people 12 to 94 years (56% of whom were older than 65 years). In this trial, the percent of people who developed symptoms confirmed to be flu were reduced from 1.4% of the participants on placebo to 0.2% for those who used Relenza.

In studies, the most common events during treatment with Relenza in adults and adolescents were:

- headaches
- diarrhea
- nausea
- ear, nose, and throat infections
- nasal irritation
- bronchitis
- cough
- sinus infections
- vomiting
- dizziness

In children, the most common side effects were ear, nose, and throat infections; vomiting; and diarrhea. Less common reported events included rashes and allergic reactions, some of which were severe.

Breathing problems, including deaths, were reported in some patients after the initial approval of Relenza. Most of these patients had asthma or chronic obstructive lung disease. Relenza, therefore, is not recommended for treatment or prevention of seasonal flu in individuals with underlying airways disease such as asthma or chronic obstructive lung disease.

Relenza has not been proven effective for treatment of influenza in people with underlying airways disease or for prevention of flu in nursing homes. The drug is also not a substitute for the flu vaccine, the primary means for preventing flu. Consumers should continue receiving an annual flu vaccination according to guidelines on immunization practices.

In preparation for a potential widespread deadly disease (pandemic), FDA has assembled an agency-wide Pandemic Influenza Preparedness Task Force to provide policy leadership and strategic planning on pandemic of flu. The Task Force is charged with developing a comprehensive plan to speed the development, production, and regulatory review of antivirals and other pandemic countermeasures.

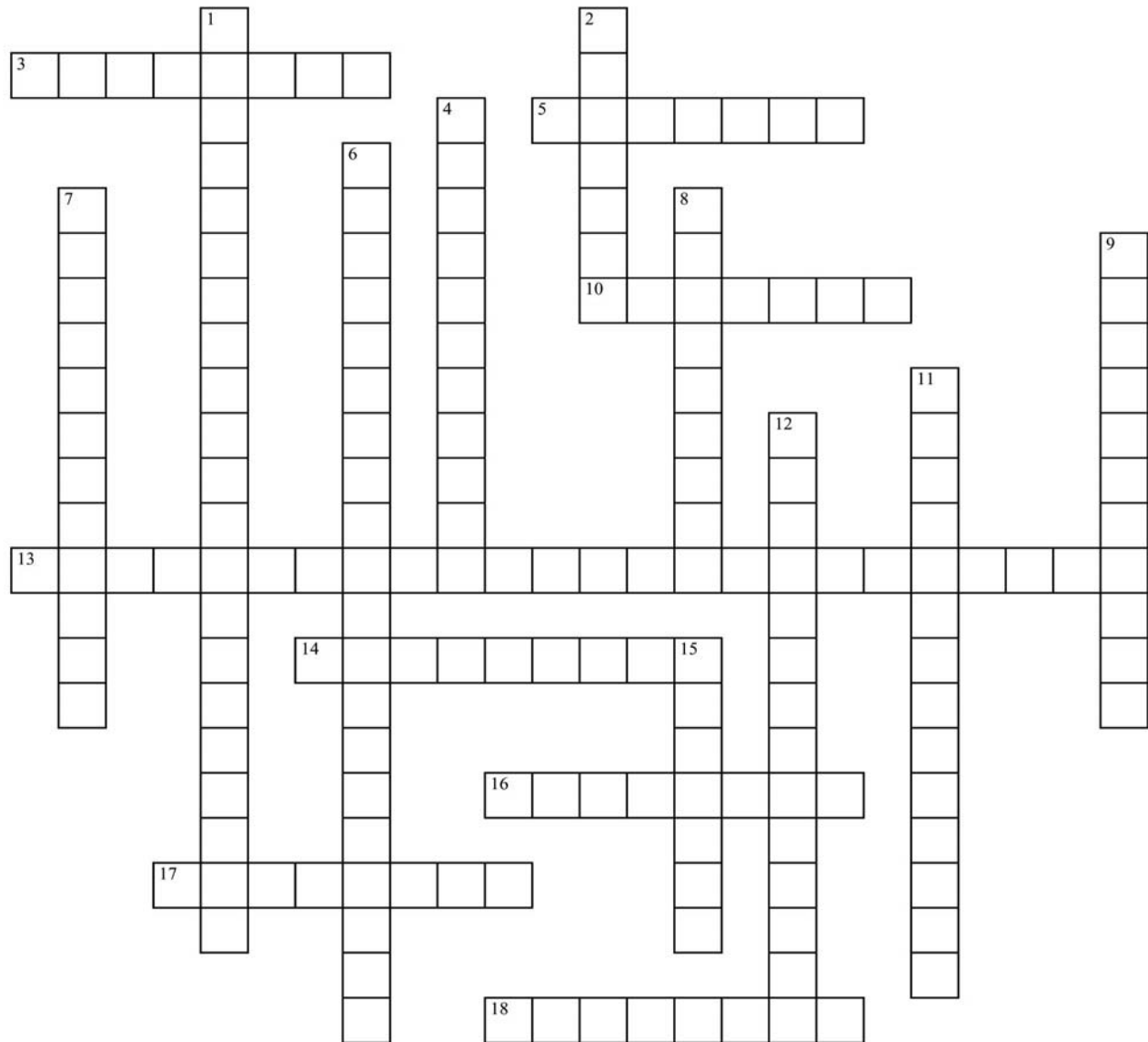
FDA also is working with the drug industry to make available appropriate products and ensure that mechanisms are in place to collect the necessary effectiveness and safety information. Both Relenza and Tamiflu have been identified for stockpiling.

For information about the flu, visit:

The Facts (from FDA's Office of Women's Health): <http://www.fda.gov/womens/getthefacts/flu.html>
What You Should Know About the Flu (CDC): <http://www.cdc.gov/flu/>

For information about the pandemic flu, visit: <http://www.pandemicflu.gov>

Maturity Health Matters - Crossword



ACROSS

- 3 What is the occurrence of potential wide-spread deadly disease called? (1 word)
- 5 What is a drug with no effect? (1 word)
- 10 What is the name of the recently FDA-approved treatment of Parkinson's Disease? (1 word)
- 13 What are the two categories of contact lenses? (5 words)
- 14 What is the largest joint in the body? (2 words)
- 16 For extended wear lenses, your eyes must rest for how long following scheduled removal? (2 words)
- 17 Patients who take Azilect should have periodic exams to check for what type of skin cancer? (1 word)
- 18 Besides diet, what can help reduce and control weight for those of any age? (1 word)

DOWN

- 1 Diets rich in whole grain foods and low in total fat and in cholesterol may reduce what two diseases? (4 words)
- 2 What is the name of the newest drug approved by FDA for the prevention and treatment of flu in adults and children five years and older? (1 word)
- 4 FDA and the drug industry have identified Relenza and Tamiflu for what protective countermeasure? (1 word)
- 6 What are the two ways that hip parts are held in place? (3 words)
- 7 What is the disease that causes bones to become brittle, crack, or break easily? (1 word)
- 8 Corneal ulcers are open sores on the cornea and can quickly, without warning, cause what serious problem? (1 word)
- 9 What is the estimated life of hip and knee replacements? (2 words)
- 11 The surgical operation that allows the ball part of the hip to be preserved and reshaped? (2 words)
- 12 What is the most common reason for joint replacement? (1 word)
- 15 What is the name of another, older drug that has been approved for prevention and treatment of flu? (1 word)

Maturity Health Matters

Maturity Health Matters is an FDA publication for older adults, their families and caregivers. We provide our readers with current information on FDA-regulated medical products. This publication can be reproduced. If you have comments about our publication, please send them to the editors.

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Special thanks to: CDER, CBER, CFSAN, and *FDA Consumer* for contributing to this issue.

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Crossword Answers

Across:

- 3 Pandemic
- 5 Placebo
- 10 Azilect
- 13 Soft and rigid gas permeable
- 14 Knee joint
- 16 One night
- 17 Melanoma
- 18 Exercise

Down

- 1 Heart disease and cancer
- 2 Relenza
- 4 Stockpiling
- 6 Cemented or uncemented
- 7 Osteoporosis
- 8 Blindness
- 9 Twenty years
- 11 Hip resurfacing
- 12 Osteoarthritis
- 15 Tamiflu

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