

High-Tech Med: The Newest Wave of Medical Innovation



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6:00 – 7:30 p.m.**

The Joseph B. Martin Conference Center
The New Research Building
Harvard Medical School
77 Avenue Louis Pasteur
Boston, MA 02115



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High-Tech Med: The Newest Wave in Medical Innovation

Moderator



Elazer R. Edelman, MD, Ph.D.

Director of Harvard-MIT Biomedical
Engineering Center
Cardiologist
Brigham and Women's Hospital
Harvard Medical School

Speakers



Conor L. Evans, Ph.D.

Assistant Professor
Wellman Center for Photomedicine
Massachusetts General Hospital
Harvard Medical School



Jeff Karp, BEng, Ph.D.

Associate Professor of Medicine
Brigham and Women's Hospital
Harvard Medical School

About the Speakers:

Elazer R. Edelman, MD, Ph.D.

Dr. Edelman and his laboratory have pioneered basic findings in vascular biology and the development and assessment of biotechnology. Dr. Edelman directs the Harvard-MIT Biomedical Engineering Center (BMEC), dedicated to applying the rigors of the physical sciences to elucidate fundamental biologic processes and mechanisms of disease. Dr. Edelman's research melds his clinical and medical training and interests, focusing on understanding how tissue architecture and biochemical regulation contribute to local growth control. Edelman and his students were among the first to validate the hypothesis that proliferative vascular diseases are the sum of effects from endogenous growth promoters and suppressors. Additional studies enabled further definition of the nomenclature and kinetics for the FGF-2 receptor complex, characterization of synergy between many growth factors, and demonstration that the mode of growth factor or inhibitor delivery determines biologic effect.

Conor L. Evans, Ph.D.

Dr. Conor L. Evans serves as an Assistant Professor at the Wellman Center for Photomedicine of Harvard Medical School at the Massachusetts General Hospital. The Evans lab's research is focused on the development and clinical translation of optical microscopy and spectroscopy tools, with specific interests in ultrasensitive detection of molecular markers, label-free imaging of tissues, and the imaging and quantification of tissue oxygenation. Dr. Evans has led the use of coherent Raman imaging technologies in biomedicine, and was the first to apply this imaging toolkit for the real-time visualization of lipids in skin in vivo. He has developed a number of imaging devices and methods, including coherent Raman imaging, time-lapse Optical Coherence Tomography, hyperspectral confocal microscopy, tissue clearing methods, and "smart" sensing bandages.

Jeff Karp, BEng, Ph.D.

Dr. Jeff Karp is an Associate Professor at Brigham and Women's Hospital, Harvard Medical School, and is Principal Faculty at the Harvard Stem Cell Institute and affiliate faculty at MIT through the Harvard-MIT Division of Health Sciences and Technology. His research harnesses materials science and stem cell biology to solve medical problems with emphasis on nanoscale/microscale materials and bio-inspired approaches. Several technologies that Dr. Karp has developed have formed the foundation for multiple products under development and for the launch of two companies, [Gecko Biomedical](#) and [Skintifique](#). Dr. Karp's work has been recognized by CNN, NPR Science Fridays, Boston Globe, ABC News, MSNBC, Fox News, CBC Quirks and Quarks, CanadaAM, BBC, LA Times, Forbes, National Geographic, Popular Science, the Washington Post, the New York Post, and by Wired Magazine.

“Bionic pancreas” could help people with type 1 diabetes control blood sugar

Posted June 17, 2014, 4:09 PM

Howard LeWine, M.D.

Chief Medical Editor, Internet Publishing
Harvard Health Publications



I take my pancreas for granted. When I eat, it pumps out insulin. This hormone helps blood sugar get into my cells. When I haven't eaten for a while, my pancreas makes another hormone called glucagon that prevents my blood sugar from dropping too low.

People with type 1 diabetes don't have this luxury. But someday they may, thanks to a bionic pancreas developed at Boston University and Massachusetts General Hospital.

In an early test of the device, reported online this week in [The New England Journal of Medicine](#), it helped control blood sugar levels in 20 adults and 32 teenagers with type 1 diabetes who went about their daily lives without the constant monitoring and injecting that's otherwise

required with this condition.

Right now, this artificial pancreas is essentially an app that runs on an iPhone wirelessly connected to a monitor worn on the abdomen that continually checks blood sugar, plus two pumps, one for insulin and one for glucagon.

The system works like this: The app on the phone tracks blood sugar. When blood sugar begins to rise, the app signals one pump to release insulin. If blood sugar falls too low, it signals the other pump to release glucagon. This is basically what happens in a healthy body.

Managing type 1 diabetes now and in the future

Type 1 diabetes is what's known as an auto-immune disease. It occurs when the body mistakenly attacks and destroys healthy cells in the pancreas that make insulin and glucagon. People with type 1 diabetes must constantly check their blood sugar and give themselves insulin. Until recently, checking was done by pricking a finger and placing blood on a small strip inserted in a meter, and insulin was administered with a shot. Today, more and more people with type 1 diabetes are checking blood sugar using a sensor worn on the abdomen and delivering insulin through an implanted pump.

Researchers Edward Damiano, an associate professor of biomedical engineering at Boston University, along with Steven Russell, an assistant professor of medicine at Harvard-affiliated Massachusetts

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General Hospital, and other colleagues used these components to build their prototype. They have begun a second round of testing, and hope to have a more sophisticated version on the market in five years.

For Damiano, the work is personal: he has a 15-year-old son who has had type 1 diabetes since he was a baby.

Many researchers around the world are searching for a way to cure type 1 diabetes. There's still no end in sight in that search. But the development of a bionic pancreas represents a bridge that would let people with type 1 diabetes control their blood sugar with less hassle, and more safely, than they do now.

To learn more...

This information was prepared by the editors of the Harvard Health Publications division of Harvard Medical School. It is excerpted from our Harvard Health Blog, available at hvrld.me/JwuR1.

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Can an app help you lose weight?

Posted November 20, 2014, 11:07 AM

Daniel Pendick

Executive Editor, *Harvard Men's Health Watch*

Smartphones and tablets combine an extraordinary amount of portable computing power with connectivity to the world via cell phone signal and WiFi. Many health entrepreneurs are trying to harness that power to help people to get healthier. According to one estimate, the number of health apps for phones may already top 40,000.

Now the tough question: Do they actually work? [A study published this week](#) in the *Annals of Internal Medicine* on one popular weight-loss app finds that the answer is “not so much.”

University of California, Los Angeles researchers put to scientific scrutiny a free app called [MyFitnessPal](#). It is based on research on how people make changes in their habits. The company claims it has more than 50 million registered users.

MyFitnessPal is a web-connected food journal and weight loss coach. A user can access a database of more than 4 million foods, and add what he or she ate to a daily log. The app calculates the number of calories consumed and compares them to the daily calorie goal, which the app computes based on the user's current weight, goal weight, and desired rate of weight loss.

The researchers randomly assigned more than 200 overweight middle-aged women to one of two groups: one used MyFitnessPal as a weight-loss aid, while the other talked to a primary care doctor about weight issues but did not use MyFitnessPal. The women's progress was assessed at three and six months—long enough to detect a significant difference in weight loss among these relatively motivated calorie counters.

The app users lost an average of about 5 pounds—but so did the non-app users. That means, at least in this study, recommending a weight-loss app to people who want to lose weight isn't much better than getting advice from a doctor. One reason may be that use of MyFitnessPal fell off quickly, from an average of 5 times a week at the start of the study to just over once a week by the second month.

Designing effective health apps

Simply giving people an app to track their data is not enough to create positive health outcomes, says Dr. Kamal Jethwani, the head of research and innovation at the [Center for Connected Health](#) at Partners HealthCare and assistant professor of dermatology at Harvard Medical School. Many health apps still lack the built-in intelligence to figure out what particular mix of features—coaching, social connections, and financial or other incentives—can provide sufficient motivation to fuel real change.

“There are many examples of apps that do one of the three right,” Jethwani says. “I have not seen one that does several things very well.”

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To help change that, Jethwani and his colleagues at the Center for Connected Health are developing a smarter app called [Text 2 Move](#) to spur healthier behaviors in people with diabetes. This dynamic phone messaging system tracks a user's activity and location, and provides him or her with personalized, motivating messages and other feedback. Preliminary research suggests it increases average walking time by a mile a day and improves blood sugar control.

The next-generation version of the app will have multiple motivation modes—coaching, social, and gamification. It will analyze a user's behavior for a short trial period and then “decide” which behavior it thinks will work best.

“We would want to have an app that, within a couple of weeks, based on your data, decides what motivational style is going to work for you and offers you a host of options,” Jethwani says.

This is more likely to succeed than depending on stressed and overtaxed health care workers to figure out the best option and “prescribe” it for you.

A health app for you?

In spite of the app's poor showing in the UCLA trial, MyFitnessPal and other health apps can be useful tools for people who want to manage their weight and lifestyle. But it takes two things from the user—motivation to make a change and using the app enough to produce the desired effect.

“Clinicians must become aware of these tools and support our patients in their use, since they are a great way to start moving the needle on the awareness and education needed to produce lifestyle changes,” says Dr. Jethwani. “Motivated patients will achieve great results, while other patients may stop using them, but will definitely gain better insights into their lifestyles.”

If you are interested in health apps, good information is available from a website called [Wellocracy](#), which is run by the Center for Connected Health. It provides tools and information to help people find apps and personal fitness trackers that suit their personal needs and motivational style.

Take a few for a test drive and see if you feel better.

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Ebola vaccine tested in African adults

News Perspectives | December 2014

Howard LeWine, M.D.

Chief Medical Editor, Internet Publishing
Harvard Health Publications

Two experimental vaccines against Ebola and Marburg viruses are safe and produced an immune response in adults in Uganda, a new study finds. This is the first time these vaccines were tested in Africa. Earlier this year, similar results were reported in healthy U.S. adults. Researchers at the National Institute of Allergy and Infectious Diseases developed these vaccines.

In the study, 108 healthy adults between the ages of 18 and 50 were randomly divided into four groups. One group got placebo injections. The other three groups got the Ebola vaccine, the Marburg vaccine, or both vaccines. The injections were given over eight weeks. Researchers followed the participants for two years. They found antibodies against the strain of the Ebola virus that caused the outbreak in West Africa in 17 of the people who got the Ebola vaccine alone and in 14 people who got both vaccines. The journal *Lancet* published the study December 23.

Years ago, I read "The Hot Zone," by Richard Preston. It was a fascinating and chilling account of how close we came to having an outbreak of an Ebola-type viral infection in the United States.

In the years since, I've read of sporadic Ebola outbreaks in places such as Gabon and Uganda. Given how far these places are from the United States, Ebola wasn't something I thought was a real threat to health here.

Yet today, serious (and realistic) worries about Ebola have reached my front door—literally. On the front door of my office, an alert has been posted asking patients to report symptoms of infection (such as fever) and recent travel to certain countries in western Africa where Ebola has been reported. It's part of a program our hospital has implemented to screen for possible cases of Ebola infection. Those considered at high risk will be isolated from other patients and staff until testing can confirm or rule out Ebola infection. Similar programs are underway at hundreds of U.S. hospitals.

Suddenly, the prospect of Ebola doesn't seem so remote.

Fortunately, there is progress to report. According to the World Health Organization, new cases of Ebola are declining in Liberia and the rising incidence in Sierra Leone may have slowed. In addition, a new study reports progress in the development of a vaccine. For a condition that (as of this writing) has recently infected more than 18,000 people, killed nearly 7,000, and has the potential to spread worldwide, positive news about a vaccine for Ebola virus can't come too soon.

Prior studies have shown that an experimental vaccine for Ebola was safe when given to healthy volunteers in the United States and that it triggered the production of antibodies that should protect against infection. This new research demonstrated similar findings among healthy adults in Uganda.

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These findings are important because:

- Vaccinations may be safe and effective in one population but not in another.
- Most cases of Ebola infection have occurred in Africa, so it's important to test the vaccine in people who may be most susceptible.
- Prevention and other public health measures (such as tracing contacts and isolating infected persons) are currently the best options for dealing with the Ebola virus.

If proven effective in those exposed to Ebola, this vaccine could save many thousands of lives.

What changes can I make now?

The most important change you can make is in how you think about Ebola and infectious diseases that may pose a threat to public health.

It's easy to be terrified about the news of the thousands of people infected with Ebola in western Africa, and about the recent cases of Ebola among travelers and health care providers in this country.

But it's important to realize that we know a lot about this virus and how to prevent its spread. In fact, Ebola is actually easier to prevent than many other infectious illnesses for two reasons. First, it takes close contact with body fluids to spread. And an infected person has symptoms (such as fever and body aches) *before* they are contagious.

There are steps you can take to reduce the already low risk of developing this disease. For example:

- Follow the news reports about where cases of Ebola have been identified—it is unlikely you would become infected if no cases have been diagnosed nearby.
- Take note of any recommendations made by local public health officials.
- Avoid nonessential travel to places where Ebola has been reported. If you must go, check the [CDC website](#) for advice about precautions you can take.
- If you're a health care worker, follow established guidelines to screen and care for potential cases of Ebola. This includes wearing protective gear and following strict protocols to avoid contact with an infected person's body fluids.

Finally, it's important to put the Ebola story in perspective. While Ebola is the big news story now, common infections such as the flu and pneumonia pose much bigger health threats in this country. There are vaccines available for these conditions, so check with your doctor to make sure that your vaccinations are up to date.

What can I expect looking to the future?

You can expect to hear much more about the development of a vaccine for the Ebola virus. Although this new study's results are encouraging, the researchers have not yet tested the ability of the vaccine to actually prevent infection.

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It's likely that the pace of research regarding Ebola will continue to accelerate. I am hopeful that such research will lead to an effective Ebola vaccine as well as more effective treatments for this devastating illness.

Ebola is getting a great deal of attention now. But it is unlikely to be the last epidemic to threaten international health. Increasing international travel and economic interdependence will continue to facilitate the spread of disease. The challenge going forward is to recognize and contain such outbreaks quickly. As the Ebola outbreak has shown, it's not easy.

To learn more...

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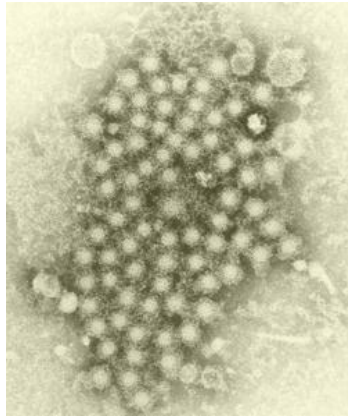
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New drugs offer easier, more effective hepatitis C treatment

POSTED APRIL 24, 2014, 11:00 AM

Daniel Pendick

Executive Editor, *Harvard Men's Health Watch*



If you are a baby boomer, the U.S. Centers for Disease Control and Prevention (CDC) recommends that you be [tested for infection with the hepatitis C virus](#). The virus can live in the liver for decades, often causing silent damage that leads to liver failure or liver cancer.

But wide-scale testing has proved to be a hard sell. One reason is that treatments to eliminate HCV infection have required weekly injections of one drug and oral doses of others. Treatment could take up to a year. Typical side effects of the injected drug required to clear the virus, called peginterferon, include depression, anxiety, irritability, anemia, and fatigue.

“The existing therapies were almost as feared as the disease itself,” says Dr. Raymond Chung, a hepatitis expert at Massachusetts General Hospital and an associate professor of medicine at Harvard Medical School.

Two drug studies published today in *The New England Journal of Medicine* mark the latest advance in making treatment for HCV easier and more effective. Researchers report that combining several oral antivirals—drugs taken in pill form, not as injections—clear the virus from the liver in more than 95% of people in just 12 weeks.

These latest reports follow FDA approvals of two oral HCV drugs in late 2011: simeprevir (Olysio) and sofosbuvir (Sovaldi). When either of these drugs is combined with injected peginterferon and an oral drug called ribavirin (Rebetol), HCV can be cleared from the liver in up to 90% of cases of the most common form of the virus (genotype 1).

The case for HCV testing

The CDC estimates that between 3 and 4 million people in the United States are chronically infected with HCV. Half may not be aware of it. The longer that HCV remains in the liver, the more likely that it will cause liver disease. One sign of this is the development of scar tissue in the liver, known as cirrhosis. An HCV infection can also lead to liver failure (requiring a transplant) or liver cancer.

Testing people born between 1945 and 1964 targets those people who have been infected long enough to be at highest risk for progression to liver disease, cirrhosis, or cancer during their lifetimes, says Dr. Chung, who wrote an editorial that accompanies the *New England Journal of Medicine* articles.

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HCV is transmitted via exposure to blood or blood products. Those most at risk of HCV infection include anyone who

- currently uses or has ever used injected drugs
- received a blood transfusion or an organ transplant before July 1992
- received clotting factor concentrates produced before 1987
- has ever been on long-term kidney dialysis.

Others at risk include health care, emergency medical, and public safety workers who were potentially exposed to HCV from needle sticks, sharps, or blood, and children born to HCV-positive women.

Screening pros and cons

Wide-scale testing of baby boomers will increase the pool of people who can benefit from the new oral drugs. “This strategy will really home in on those who are at greatest risk of disease,” Dr. Chung says. “If fully implemented, it might be able to identify another million people previously undiagnosed with hepatitis C.”

Not everyone with chronic HCV infection develops liver disease or liver cancer. But they can still spread the infection to others. Also, once a person develops cirrhosis or significant liver damage, successful antiviral treatment may not eliminate the lifetime risk of premature death from liver disease or cancer as much as treating it earlier in the course of disease.

Price remains an obstacle

In an era of safe, highly effective antivirals and a treatment time that may shrink to 8 weeks with tolerable side effects, many barriers to HCV treatment are falling.

Except for one: cost. Currently the cost of oral therapy tops \$80,000. “The irony is that we have solved the scientific challenge of HCV, but now the bottleneck lies in getting those pills into the patient,” Dr. Chung says. “That’s where cost enters the room.”

With even more oral drugs expected to be approved by the end of 2014, Dr. Chung says, there is hope that competition for a growing pool of HCV-infected people will help to drive costs down.

“Now that we have a treatment that would succeed in the vast majority of people with few side effects and a shorter treatment time, it would be a shame to miss out on curing someone who might later present with advanced disease,” Dr. Chung says.

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High-tech ways to better shoe fit

Relieving pain in your knees, hips, and back may begin with your feet.

If you're looking to update your athletic shoes before going for a walk or run in the warmer weather, you may be tempted to try out some high-tech machines in specialty shoe stores that boast a better fit. Do they really work? "Yes, but technology is only as valuable as the person interpreting the data," says David Nolan, a physical therapist with the Orthopaedics Sports Performance Center Running Program at Harvard-affiliated Massachusetts General Hospital.

The right support in your shoes can stave off foot problems that can lead to knee, hip, and back problems and raise the risk of falls and fractures. New high-tech machines in shoe stores can point out where you need that support.

The machines fall into two categories: foot scanners and gait analyzers. Scanners are usually computerized mats you stand on that map the pressure points on the soles of your feet. This map can help determine your arch type and whether you need special arch supports called orthotics. Gait analyzers record the characteristics and support needs of your feet in motion. The machines range from computerized mats to treadmills with video cameras. It takes a trained salesperson "with an understanding of shoe construction and the mechanics of mobility to get the fit right," says Nolan. "Many people in the shoe industry have some training to successfully assess most people."

Better walking or running shoes can help you reach the recommended weekly goal of 150 minutes of moderate-intensity physical activity—such as brisk walking—without foot pain or the risk of foot problems.

To learn more...

This information was prepared by the editors of the Harvard Health Publications division of Harvard Medical School. It is excerpted from the March 2013 issue of the *Harvard Health Letter*, available at hvrld.me/JwyQ2.

High-tech heart scans not always helpful

Doing high-tech heart scans on people at above-average risk of heart problems sounds like common sense, but it often doesn't add much benefit to just taking necessary medications, staying fit, eating healthy, and not smoking. This is one take-home message from a study in *The Journal of the American Medical Association*, which involved a group of people long known to be at higher cardiac risk: middle-aged adults with diabetes.

The 900 study participants were already being treated with medication and other measures to lower their blood sugar. They had no existing symptoms of clogged arteries, like chest pain or past heart attacks. Half were chosen at random to have CT angiography, a scan that can reveal cholesterol-rich deposits that lead to heart attacks.

The scans allowed doctors to step up efforts to lower "bad" LDL cholesterol and blood sugar in the higher-risk individuals and hopefully prevent heart attacks. But after four years, the people who had been singled out for extra care were not better off than those who were not scanned. It's possible that people in the study were already receiving such good care that stepping it up based on heart scans didn't improve the results enough to show a difference.

To learn more...

This information was prepared by the editors of the Harvard Health Publications division of Harvard Medical School. It is excerpted from the February 2015 issue of the *Harvard Men's Health Watch*, available at hvrld.me/JwB58.

High-tech scan reveals protein in the brain linked to Alzheimer's disease

A special form of PET scanning offers a more certain diagnosis for some, but at a steep out-of-pocket cost.

A new kind of brain scan can detect beta amyloid, an abnormal protein associated with Alzheimer's disease. It can be helpful when, based on symptoms and a careful assessment, your doctor suspects Alzheimer's disease but remains unsure of the final diagnosis. "If your doctor suspects that the underlying cause of your cognitive deficits is Alzheimer's disease, then a scan like this can help corroborate that," says Dr. Gad Marshall, an assistant professor of neurology at Harvard Medical School. "It can help with the hard-to-call cases."

The major catch is that Medicare and private insurance don't generally cover the cost of the test, which could exceed \$3,000. But for those able to pay, the scan could provide more time to come to terms with a diagnosis of Alzheimer's and plan for future health care.

Alzheimer's diagnosis: Next steps

Seeking a prompt diagnosis of Alzheimer's disease is an opportunity for helpful actions. Here are the potential benefits, according to the Alzheimer's Association:

- **Get the maximum benefit from available treatments.** You can explore treatments that may provide some relief of symptoms and help you maintain a level of independence longer. You may also increase your chances of participating in clinical drug trials that help advance research.
- **Have more time to plan for the future.** An early diagnosis of Alzheimer's allows you to take part in decisions about care, transportation, living options, and financial and legal matters. You can also participate in building the right care team and social support network. To get help with creating a personalized action plan, contact the Alzheimer's Association at 800-272-3900 or www.alz.org.
- **Seek support for you and your loved ones.** Care and support services are available, making it easier for you and your family to live the best life possible with Alzheimer's or dementia.

When a scan helps

The test is a form of positron emission tomography (PET). Before the scan, the person gets an injection of a chemical tracer, florbetapir (Amyvid), which latches onto amyloid in the brain. The PET scan shows the size and location of amyloid deposits.

About 30% of people in their 70s have amyloid in their brains, yet their minds and memories still function within the normal range. For this reason, amyloid PET is not yet useful as a general "just in case" test for Alzheimer's disease. "The scan is for people with symptoms of mild cognitive impairment

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(MCI) or full-blown dementia,” Dr. Marshall says. (MCI is a “pre-dementia” that usually develops before Alzheimer’s.)

Especially in the earliest stages, Alzheimer’s disease can affect a person’s mind, memory, and behavior in ways that resemble those of other medical conditions—for example, damage to small blood vessels in the brain that can affect cognitive function. Or, the person could be suffering from a type of dementia other than Alzheimer’s that requires a different treatment approach.

A tentative diagnosis of Alzheimer’s leaves people and their families in a fearful state of limbo. In such cases, an amyloid scan could be beneficial. “It tells you if a significant amount of amyloid is present,” Dr. Marshall says. “If so, Alzheimer’s disease would be the likely cause of the impairment, instead of some other neurological problem.”

Proponents of more widespread use of amyloid PET say it could help to prevent people being misdiagnosed with Alzheimer’s disease, leading to delayed or inappropriate treatments. That could make a difference if the missed diagnosis is something like Parkinson’s disease, for which there are more effective treatments.

But there is also an important potential benefit of amyloid PET that lies beyond the basic medical issues. Alzheimer’s disease is not a diagnosis anyone wants, but knowing one way or the other can allay fears and allow people to come to grips with the disease and start to prepare for what’s to come. “I think that is very important for a lot of people, and for some it’s vital,” Dr. Marshall says. “Just not knowing causes them and their caregivers a lot of stress. Also, having a clearer diagnosis helps patients and their caregivers plan for the future.”

Who can get the test?

There is no cure yet for Alzheimer’s, and the medications available to treat its symptoms offer a modest benefit at best. Because the ultimate medical benefit of amyloid PET is so limited, the Centers for Medicare and Medicaid Services (CMS) has so far declined to pay for amyloid PET scans outside of research studies. Private insurers generally follow CMS’s lead. Unless the federal policy changes, amyloid PET scans will remain an out-of-pocket expense for most people.

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The search for better ways to find and treat prostate cancer



Biomarkers for better screening

Biomarkers are molecular signatures of both normal and abnormal processes in the body. Proteins, fragments of proteins, enzymes, DNA, and the RNA molecules that “read” DNA can all serve as biomarkers. Blood is an ideal source material because it’s easy to collect and examine, but biomarkers can also be found in other body fluids, like urine, and in tissue itself. Biomarkers can inform decisions before, during, and after treatment.

More and better biomarkers are needed for many medical conditions, but especially for prostate cancer. Too many screenings result in biopsies that might have

been avoided. Too many slow-growing cancers are treated that didn’t need to be because they weren’t likely to cause any harm.

We already have a screening biomarker for prostate cancer: PSA, or prostate-specific antigen, a protein released by prostate tissue. The screening test measures levels of PSA in the blood. But the PSA test has two major problems. It’s specific for the prostate but not for prostate cancer, so high levels may indicate not cancer but benign prostatic hyperplasia (BPH) or some other problem related to the prostate. In addition, even when high PSA levels are a reliable indication of prostate cancer, the PSA test does not distinguish between aggressive cancers that need to be treated and indolent ones that don’t need to be treated because they’re growing slowly.

Currently, the diagnosis of prostate cancer hinges on biopsies—and whether cancer cells are found in the tiny pieces of tissue that are collected. But when PSA levels are elevated but not extremely high, about three out of every four biopsies come back negative. Urine-based tests could prevent unnecessary biopsies by indicating whether prostate cancer is present.

PCA3. When prostate cells become cancerous, their prostate cancer antigen 3 (PCA3) genes become overactive and produce telltale amounts of RNA molecules that “read” DNA. Some of that RNA leaks into the urine in amounts that can be detected. Only prostate cancer cells produce PCA3 RNA, so unlike the PSA test, the PCA3 test is specific to cancer.

The FDA approved the PCA3 test two years ago for men ages 50 and older who have had one or more previous negative biopsies. The test is intended to help men and their doctors decide whether a repeat biopsy should be done. Eventually, though, the test might be used to determine whether a biopsy is needed in the first place.

TMPRSS2:ERG gene fusion. When two genes—TMPRSS2 and ERG—switch places and fuse together, the result is known as the TMPRSS2:ERG fusion. This genetic rearrangement is found in about half of all prostate cancers, and measurable amounts of RNA from this fusion are present in urine. The TMPRSS2:ERG fusion is highly specific to prostate cancer—that’s the good news. But because it’s

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present in only half of prostate cancers, depending on it as the only biomarker would miss a lot of prostate cancers.

Results from several studies over the last couple of years have shown that combining the PCA3 test with the TMPRSS2:ERG fusion test is a promising approach. Findings presented in 2013 at a European meeting of urologists showed that when the results of the two tests are combined, a low score reliably indicates a small (less than 5%) chance of significant cancer, so a biopsy might not be necessary. A high score indicates a significant chance (about 80%) of high-grade cancer, so a biopsy as a next step would make sense.

Treating prostate cancer

One thing is certain about treating prostate cancer: it's very complicated. Often there is no obvious best choice, and patients need to weigh their options carefully and make a decision based on many factors—not only the stage of their cancer, but also their age, lifestyle, and risk of side effects such as urinary incontinence and erectile dysfunction. In many cases, patients can safely opt for no treatment at all. But researchers are always pushing the boundaries and looking for new ways to treat prostate cancer, especially late-stage cancers that have spread beyond the prostate. The following are just a few of the many new treatments that hold promise.

Hormone therapy

Androgens, the family of male sex hormones that includes testosterone, function as a fuel for growth in normal development. However, in some men they can also drive the progression of prostate cancer. Hormone therapy treats prostate cancer by dramatically reducing levels of testosterone and other androgens.

In the past, hormone therapy meant the surgical removal of both testicles, which produce sperm and testosterone. Although commonly called castration, the formal medical term is orchiectomy (orchis is Greek for testis). Because more than 90% of androgens are produced in the testicles, orchiectomy immediately ceased production of most of the hormones fueling the growth of prostate cancer cells. But understandably, many men find the idea of having their testicles removed difficult to accept, and because the procedure can't be reversed, doctors now use drugs to dramatically lower androgen levels and slow prostate cancer.

Therapies that work in the pituitary gland

One class of drugs often used in hormone therapy, called luteinizing hormone–releasing hormone (LHRH) agonists, works in the pituitary gland, the pea-size gland that hangs off the base of the brain. The pituitary gland's nickname is the master gland because the hormones it secretes orchestrate the activity of other glands and hormones.

LHRH agonists inhibit the production of luteinizing hormone (LH) in the pituitary gland. Because LH stimulates testosterone secretion in the testicles, inhibiting it lowers testosterone levels. LHRH agonists are injected into muscle or fat tissue under the skin. The first LHRH agonists were self-injected by patients on a daily basis. Today, formulations are available that can be implanted under the skin to

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High-Tech Med: The newest wave of medical innovation

Longwood Seminars, March 10, 2015

provide extended release of the medication for anywhere from a month to a year. However, they can cause a temporary surge in testosterone that generally lasts from three to four weeks. During this period, symptoms may worsen, a situation known as a “clinical flare.”

Gonadotropin-releasing hormone (GnRH) antagonists are another option for lowering testosterone levels by manipulating the pituitary gland. Two GnRH antagonists are currently available: degarelix (Firmagon) and abarelix (Plenaxis), the latter of which was developed in part by Dr. Marc Garnick, clinical professor of medicine at Harvard Medical School and a top prostate cancer expert at the Hematology/Oncology Division of Beth Israel Deaconess Medical Center. These drugs block the release of luteinizing hormone just as LHRH agonists do, but they do not trigger a testosterone surge.

A study published in 2012 suggests that abarelix—which works fast—might even be worth trying first. The researchers found that 12 weeks of abarelix treatment reduced testosterone levels to castration levels in 94% of the men. During the same period, PSA levels decreased significantly. Participants then took an LHRH agonist for another eight weeks. Testosterone levels and PSA remained stable during that period. Although abarelix is not currently available in the United States, this study showed that using a GnRH antagonist, followed by an LHRH agonist, might be good approach to treating advanced prostate cancer—and in the United States, degarelix could be used instead of abarelix. This strategy might help men with a high PSA (greater than 20 ng/ml) or metastatic disease causing pain and other symptoms.

Bone-targeting treatments

When prostate cancer spreads (metastasizes) from the prostate, it spreads to the bone about 90% of the time. Often, prostate cancer’s most serious—and sometimes deadliest—consequences are the toll it takes on bone tissue. So one promising strategy for treating prostate cancer is to control the disease once it has entered bone tissue. One new drug following that strategy is called radium-223 (Xofigo).

The FDA approved radium-223 in May 2013, but the medication seems to come out of science fiction. It attacks prostate cancer lurking in bone by exposing it to high-energy alpha-particle radiation. The alpha particles emitted by the compound are potent enough to scramble the DNA of prostate cancer cells, but they travel a tiny distance—less than 100 micrometers, which is about a quarter of the diameter of the period at the end of this sentence. As a result, the effects on nearby healthy bone marrow are limited, so there should be fewer side effects than with previous treatments.

Radium-223 has a relatively short half-life of about 11 days. Because of its chemical similarity to calcium, once it’s in the body (it’s administered by injection into a vein), the drug travels to and stays in bone tissue.

Results of an industry-sponsored Phase 3 trial of radium-223 were published in 2013. A total of 921 men were randomly assigned to receive six intravenous injections of either radium-223 or a placebo. The injections were given four weeks apart. The main outcome was that men who received radium-223 lived longer than men who received the placebo (14.9 months vs. 11.3 months). That may seem like a small difference, but these men had advanced prostate disease with a high mortality rate, so even small survival gains are important.

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The FDA had approved radium-223 for the treatment of men with advanced prostate cancer that has spread to the bone, not to other organs, and only after efforts to control the prostate cancer with hormones have failed. But there's a good chance that radium-223 will eventually be used in other circumstances and earlier in the course of a man's disease.

To learn more...

This information was prepared by the editors of the Harvard Health Publications division of Harvard Medical School. It is adapted from our *Annual Report on Prostate Diseases*, available at hvr.d.me/Jx3yd.

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Prickly Porcupine: Medicine's Next Top Model?

The North American porcupine is easily recognizable due to its impressive coat of long, sharp quills. These unique projections are designed so that they can easily penetrate animal flesh, but are extremely difficult to remove. While this may be bad news for a predator or a curious pet, this natural mechanism is a boon for a curious medical researcher trying to develop a better medical device.

A research team led by Jeffrey Karp, PhD, Brigham and Women's Hospital (BWH) Division of Biomedical Engineering, Department of Medicine, collaborating with Massachusetts Institute of Technology's (MIT) Robert Langer, PhD, have figured out the secret to the porcupine quill's easy-in, not-so-easy-out design and demonstrated how that design could be applied to developing a better medical needle or adhesive patch.

The researchers worked with natural porcupine quills and molded polyurethane quills (mimicking the structure of natural quills) to help them understand the forces involved. They discovered that a quill's geometry, particularly its sleek backward facing barbs, is instrumental in its ability to easily penetrate tissue and subsequently prevent easy extraction.

The barbs appear to act like serrated blades on the way in, localizing force at the tips of the barbs to make it easy to slice through tissue. On the way back out, however, the barbs act like hooks that snag the flesh. "We were most surprised to find that the barbs on quills serve a dual function," says Karp. "Namely, the barbs reduce the penetration force for easy insertion into tissue and maximize the holding force to make the quills incredibly difficult to remove."

And the concentration of barbs toward the tip also appears to play a role. "By carefully removing the barbs from the quill, we discovered that, in addition to their physical features, the location of barbs on the quill played a major role in minimizing penetration forces and maximizing the work needed to yank them from the tissue," explains Woo Kyung Cho, PhD, BWH Division of Biomedical Engineering, Department of Medicine, study first author.

Such contrary forces would work well for a medical needle, enabling it to penetrate human skin easily (causing less trauma) and helping to ensure that the needle stays in place and doesn't buckle. Similarly, a patch with a proliferation of tiny porcupine-like barbs on its lower surface could easily attach to the skin and stay there without the aid of sticky chemical adhesives.

"We developed plastic replicas that remarkably mimicked the reduced penetration force and increased pullout," says Dr. Karp. "This should be useful to develop next-generation medical adhesives and potentially design needles that cause less pain."

Karp's team has already made significant progress in the next step of the design process, which is to find a way to loosen the barbs' hold. One approach has been the development of a biodegradable substance that stays strong for a period of time, but then breaks down gradually and eventually makes it easy to remove the needle or patch. They're also working with a substance that swells, thereby dulling the sharpness of the barbs and loosening their grip.

Karp's team expects that it won't be long before their synthetic quill lab work is adapted for use in a clinical setting – and then they'll get back to exploring nature for the next way to improve patient care.

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Bio-inspired glue keeps hearts securely sealed

Adhesive may improve the way surgeons treat congenital heart defects and other heart problems

January 8, 2014

By Marjorie Montemayor-Quellenberg, BWH Communications
(From Harvard Gazette)

Surgeries which demand that devices be quickly and safely secured inside the heart have long presented challenges to doctors working on children born with defects such as a hole in the heart. Sutures take too long to stitch and can stress the fragile tissue, and clinical adhesives can be toxic or lose their sticking power in blood or under dynamic conditions, such as within a beating heart.

“About 40,000 babies are born with congenital heart defects in the United States annually, and those that require treatment are plagued with multiple surgeries to deliver or replace nondegradable implants that do not grow with young patients,” said Jeffrey Karp of the Division of Biomedical Engineering, BWH Department of Medicine, and an associate professor at Harvard Medical School (HMS).

To address that problem, Karp and researchers from Harvard-affiliated Children’s Hospital Boston and Brigham and Women’s Hospital and the Massachusetts Institute of Technology (MIT) have developed a bio-inspired adhesive that they say can rapidly attach biodegradable patches inside a beating heart — in just the places where holes occur in conditions such as ventricular heart defects. Their preclinical study of the adhesive was published today in *Science Translational Medicine*.

Recognizing that many animals secrete viscous, water-repelling substances that enable them to attach under wet and dynamic conditions, the researchers developed a material that has these properties and is also biodegradable, elastic, and biocompatible. According to the study authors, degradable patches secured with the

glue remained attached even when heart rate and blood pressure were increased.

“This adhesive platform addresses all of the drawbacks of previous systems in that it works in the presence of blood and moving structures,” said Pedro del Nido, chief of cardiac surgery at Children’s Hospital Boston, the William E. Ladd Professor of Child Surgery at HMS and, with Karp, the study’s co-senior author. “It should provide the physician with a completely new, much simpler technology and a new paradigm for tissue reconstruction to improve the quality of life of patients following surgical procedures.”

Unlike currently available surgical adhesives, the new adhesive maintains very strong sticking power in the presence of blood, and even in active environments. Importantly, its adhesive abilities are activated with ultraviolet (UV) light, providing an on-demand, anti-bleeding seal within five seconds of UV light application when applied to high-pressure large blood vessels and cardiac-wall defects.

“This study demonstrated that the adhesive was strong enough to hold tissue and patches onto the heart equivalent to suturing,” said co-first author Nora Lang, Department of Cardiac Surgery, Children’s Hospital Boston. “Also, the adhesive patch is biodegradable and biocompatible, so nothing foreign or toxic stays in the bodies of these patients.”

“When we attached patches coated with our adhesive to the walls of a beating heart, the patches remained despite the high pressures of blood flowing through the heart and blood vessels,” said Maria N. Pereira, the co-first author. Pereira had worked in the Karp Lab at BWH while a Ph.D. student in the MIT-Portugal Program, and now directs adhesive technology at Gecko Biomedical, to which the developers have licensed the adhesive for further development.

The Paris-based start-up company raised €8 million in a recently announced Series A financing round and expects to bring the adhesive to market within two to three years.

The researchers note that their waterproof, light-activated adhesive will be useful in reducing the invasiveness of surgical procedures, as well as operating times, in addition to improving heart-surgery outcomes.

“We are delighted to see the materials we developed being extended to new applications with the potential to greatly improve human life,” said Professor Robert Langer of MIT, another author of the study.

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<http://news.harvard.edu/gazette/story/2014/01/bio-inspired-glue-keeps-hearts-securely-sealed/>

Stuck on You

by Susan Karcz

(from Harvard Medicine Magazine: Food Issue: Diet and Health Issue)

The little green lizard that hawks insurance may have unusual skills, such as the ability to speak, but a team of HMS and MIT researchers, who have been investigating the capabilities of the gecko, has been inspired by a different attribute—the unique gripping properties of the animal's feet. The team, led by Jeffrey Karp, an HMS assistant professor of medicine at Brigham and Women's Hospital, and Robert Langer, an HMS senior lecturer on surgery and the David H. Koch Institute Professor at MIT, has developed a snug-fitting surgical-grade adhesive bandage that may replace or augment traditional methods of closing surgical wounds, such as with sutures or staples. Karp and his team developed a bandage that meets the requirements for surgical applications—biocompatible, biodegradable, and elastic—by using a biorubber that can conform to the tiny hills and valleys of tissue surfaces.

Like the feet of the gecko, which can grip in vertical or inverted positions, this bandage can adhere to uneven surfaces in wet environments, such as human internal organs. Unlike a gecko's grip, this bandage does not need to be removed for it dissolves harmlessly in the body, making it a viable tool for surgical repairs such as patching a hole from a gastric ulcer. The adhesive could even be infused with drugs or growth factors and "tuned" for specific surgical uses.

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Bioengineered 'Band-Aids' Patch Damaged Arteries

May also be used for wound healing, diabetes, and to replace faulty tissues

By William J. Cromie

Gazette Staff

(From Harvard Gazette Archives)

A way to treat rapid clogging of arteries by putting bandages on their exteriors is being developed by bioengineers at the Medical School and M.I.T.

The inside-out technique repairs the interior of damaged arteries by wrapping them with plastic patches holding cells normally found only in the inner lining.

Such patches might also accelerate wound healing, provide missing insulin-producing cells for diabetics, and even regrow lost bone, cartilage, and liver tissue.

"If successful, this technique could allow us to implant cells so they treat a disease the way the body would treat it, if it could," noted Elazer Edelman, associate professor of medicine at Brigham and Women's Hospital. "Rather than continually giving large doses of a single drug, we could put in something once that provides all the compounds secreted by natural cells."

Accelerated Atherosclerosis

The bioengineered band-aids came out of an attempt to solve one of the most serious problems in the treatment of heart disease. Surgeons perform some 1.5 million operations a year to clear arteries blocked by fatty, fibrous growths. They squeeze the clots out of the way with tiny inflatable balloons (angioplasty), bypass the obstructed vessels with leg

veins, or install metal coils to prop them open. Thirty to 50 percent of these repair jobs fail in less than a year.

"The average age of a person having a heart attack is 58 years," notes Edelman. "So it takes 50 to 60 years to develop the first serious blockage of a coronary artery. But 30 to 50 out of every 100 arteries we repair develop accelerated atherosclerosis and they can become reblocked in 3 to 6 months."

Edelman and some colleagues at the Harvard-M.I.T. Division of Health Sciences and Technology (HST) narrowed the problem to the thin lining of cells on the inside of all blood vessels. Called the endothelium, this lining becomes torn at the site of surgery done to clear blockages. The tear exposes smooth muscle cells underneath, which start to multiply rapidly. Ordinarily, contraction and expansion of these muscle cells moves blood through the vessel, but their overgrowth in the absence of a lining obstructs the artery.

Cells in the endothelium normally secrete a substance that controls this growth. Ripping the cells away removes that brake. It also stimulates muscle cells to increase production of a protein growth factor. That's like stepping on the accelerator.

"You get a dual combination of growth inhibition and growth stimulation," explains Edelman. "It's a one-two punch that doesn't stop until the endothelium repairs itself."

Working with Morris Karnovsky, Shattuck Professor of Pathological Anatomy, Edelman learned about heparin sulfate, a natural substance secreted by endothelial cells to retard clotting. Replacing the heparin compound would be an obvious way to treat the problem. Dutch cardiologists, for example, put heparin coatings on the flexible metal coils they use to keep arteries open.

Harvard researchers took things one step further. They found that endothelial cells secrete many other compounds, and that combination should do a better patching job than heparin sulfate alone.

"Karnvosky made the key discovery that the cells are not just a physical barrier separating blood flow and smooth muscle cells, but a biochemical factory that manufactures a variety of products to keep blood vessels healthy," Edelman said.

Together with other research teams, they tried paving over the potholed lining with whole cells. It didn't work.

"The cells didn't stay in place," Edelman recalled. "They were gone in three days."

Living Plastic Pavement

Then Edelman had an amazing idea. Since the paving process was chemical, not just physical, why not put the inner cells on the outside and let the healing salves work their way inward?

Edelman earned his Ph.D. with Robert Langer, a faculty member of HST and an expert on combining biodegradable plastics with drugs. As the plastic degrades, it releases a continuous dose of drugs at a targeted site. Edelman reasoned that he could use the same technique to make a thin, spongelike bandage that would hold endothelial cells in its pores rather than drugs.

He and his colleagues inserted cells from the arteries of cows into the bioengineered gauze and wrapped it around damaged neck arteries in rats.

The technique worked.

"The chemically active implant reduced abnormal growth of muscle cells by more than 90 percent, far more than the use of a single compound like heparin," Edelman reported recently in the Proceedings of the National Academy of Sciences. "To our knowledge, this is the first use of such implants to control blood vessel disease. The work demonstrates that the release of a full set of compounds from intact endothelial cells is far superior than the release of a single cell product given as a drug."

This work was done with Aruna Nathan, while she was a postdoctoral fellow at M.I.T., and Professor Matthew Nugent of the Boston University School of Medicine.

Tests on pigs will come next. "Their hearts are similar to ours," Edelman explains. Some problems remain, however, before the bioengineered bandages can be implanted in humans.

"We need a better understanding of what molecules endothelial cells produce and their role in the healing process," Edelman says. "Also, some arteries, particularly small ones in the heart, are difficult to dig out surgically and surround with implants."

However, these unresolved questions have not deterred him and others from working on other aspects of tissue engineering. "These same techniques might be used for treating large wounds, and for correcting the chemical deficiencies of Parkinson's disease and diabetes," Edelman says.

Degeneration of brain cells leads to the failures of muscle control that is characteristic of Parkinson's. The hope is that replacement cells can be embedded in a biodegradable plastic and placed in the brain. Experiments with animals indicate that such implants stay in place when simply laid in position.

It might also be possible to replace the faulty insulin-secreting cells that cause diabetes, Edelman believes.

Langer is working on the idea of using cell patches to renew lost bone and cartilage in people suffering from injuries, osteoporosis, and arthritis.

Joseph Vacanti, associate professor of medicine at Children's Hospital, leads a team researching liver transplants made from plastic sponges "soaked" in donor liver cells. Properly nourished with blood, a relatively small number of such cells might grow into a full-sized liver.

Edelman finds such potential "both intellectually and practically appealing. These techniques offer natural rather than pharmacological

control of disease. We could implant something once that would restore a natural function rather than have patients taking large doses of medication over a long period or a lifetime."

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Pill-sized device rivals endoscopy

Novel imaging system screens for Barrett's esophagus in minutes

January 13, 2013 | Editor's Pick MGH

By Sue McGreevey, Massachusetts General Hospital Public Affairs
(from Harvard Gazette)

Physicians may soon have a new way to screen patients for Barrett's esophagus, a precancerous condition usually caused by chronic exposure to stomach acid. Researchers at the Wellman Center for Photomedicine at Massachusetts General Hospital (MGH) have developed an imaging system enclosed in a capsule about the size of a multivitamin pill that creates detailed, microscopic images of the esophageal wall. The system has several advantages over traditional endoscopy.

"This system gives us a convenient way to screen for Barrett's that doesn't require patient sedation, a specialized setting and equipment, or a physician who has been trained in endoscopy," says Gary Tearney of the Wellman Center and the Pathology Department at MGH, a Harvard affiliate, a professor of pathology at Harvard Medical School and the corresponding author of the report receiving online publication in *Nature Medicine*. "By showing the three-dimensional, microscopic structure of the esophageal lining, it reveals much more detail than can be seen with even high-resolution endoscopy."

The system developed by Tearney and his colleagues involves a capsule containing optical frequency domain imaging (OFDI) technology — a rapidly rotating laser tip emitting a beam of near-infrared light and sensors that record light reflected back from the esophageal lining. The capsule is attached to a stringlike tether that connects to the imaging console and allows a physician or other health professional to control the system. After the capsule is swallowed by a patient, it is carried down the esophagus by normal contraction of the surrounding muscles. When the capsule reaches the entrance to the stomach, it can be pulled back up by the tether. OFDI images are taken throughout the capsule's transit down and up the esophagus.

An inch-long endomicroscopy capsule contains a rotating infrared laser and sensors for recording reflected light.

The researchers tested the system in 13 unsedated participants, six known to have Barrett's esophagus and seven healthy volunteers. The physicians operating the system were able to image the entire esophagus in less than a minute and a procedure involving four passes — two down the esophagus and two up — could be completed in around six minutes. A typical endoscopic examination requires that the patient stay in the endoscopy unit for approximately 90 minutes. The detailed microscopic images produced by the OFDI system revealed subsurface structures not easily seen with endoscopy and clearly distinguished the cellular changes that signify Barrett's esophagus. Study participants who had previously undergone endoscopy indicated they preferred the new procedure.

“The images produced have been some of the best we have seen of the esophagus,” says Tearney, an MGH Research Scholar. “We originally were concerned that we might miss a lot of data because of the small size of the capsule; but we were surprised to find that, once the pill has been swallowed, it is firmly ‘grasped’ by the esophagus, allowing complete microscopic imaging of the entire wall. Other methods we have tried can compress the esophageal lining, making it difficult to obtain accurate, three-dimensional pictures. The capsule device provides additional key diagnostic information by making it possible to see the surface structure in greater detail.”

Current recommendations for diagnosis of Barrett's esophagus, which is uncommon in women, call for endoscopic screening of men with chronic, frequent heartburn and other symptoms of gastroesophageal reflux disease. Harvard Associate Professor of Medicine Norman Nishioka of the Wellman Center and MGH Gastroenterology, one of the study co-authors, notes, “An inexpensive, low-risk device could be used to screen larger groups of patients, with the hope that close surveillance of patients found to have Barrett's could allow us to prevent esophageal cancer or to discover it at an earlier, potentially curable stage. But we need more studies to see if that hope would be fulfilled.”

Additional co-authors of the Nature Medicine report are the lead author Michalina Gora, Robert Carruth, Kevin Gallagher, Lauren Kava, Mireille Rosenberg, and Brett Bouma of the Wellman Center; Jenny Sauk, MGH Gastroenterology; and Melissa Suter, MGH Pulmonology. Support for the study included National Institutes of Health grants.

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CBS Interactive (CNET) - Michael Franco

<http://www.cnet.com/news/paint-on-bandage-changes-color-as-your-wound-heals/>

The Edelman Lab: Harvard-MIT Biomedical Engineering Center

<http://edelmanlab.mit.edu/research>

The Evans Lab Research

<http://www2.massgeneral.org/wellman/faculty-evans-projects.htm>

Wellman Center of Photomedicine: Why Light?

<http://www2.massgeneral.org/wellman/about-why-light.htm>

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