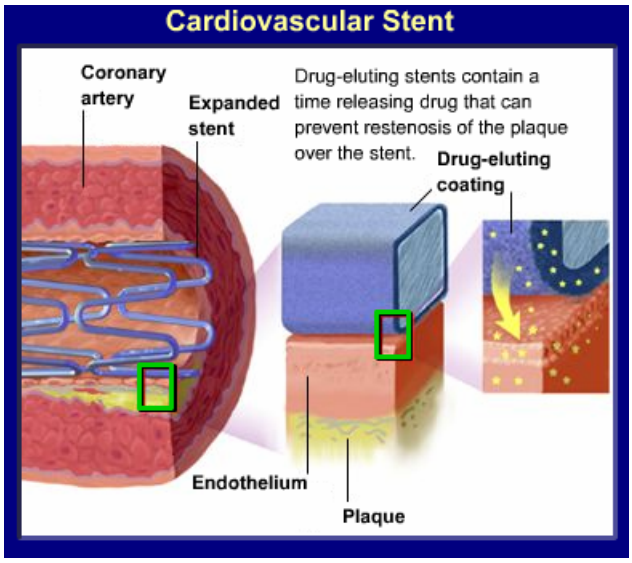
Paclitaxel-coated Stents: A Way to Bypass By-Pass Surgery

This particular case study is a unique example where the combination of two existing products, in this case paclitaxel (drug) and stent (device) proved valuable to treating a disease - coronary disease.

For several years, stents (tiny mesh tubes made out of soft but sturdy metals) have been used in surgical procedures to prop open arteries after the blood vessels have been cleared of blockages by balloon angioplasty. Unfortunately, scar tissue often forms near the implanted stent that can cause the artery to re-clog or restenose in approximately 10 to 40 percent of patients.

In one of the latest surgical technology revolutions, cardiac stents are now being coated with paclitaxel to produce dramatically better outcomes for patients. Paclitaxel is perhaps best known in the form offered by Bristol-Myers Squibb (BMS) as the drug Taxol®. "Taxol embedded in a polymer on the stent itself modifies the healing process, so that scar tissue does not build," commented John Groetelaars, vice president for Boston Scientific Canada, a leading developer of drug-eluting stents. The polymer has a time-release mechanism, so that the drug can be dispensed or eluted into the tissue nearby. This has dramatically reduced restenosis rates to just 3 to 6 percent, meaning far fewer return visits to the catheterization lab or operating room for cardiac patients[1].



Taxol®, originally discovered in the 1960s, and its equivalents are currently the most successful anti-cancer drugs on the market[2]. However, nobody thought of using paclitaxel to prevent arterial re-clogging until, over lunch, the inventors Dr. Sollott and Dr. Kinsella brainstormed this very idea. According to Dr. Kinsella, the idea was to use Taxol® at a lower concentration than used for cancer treatment so that it did not kill cells but only modified their activity. The experiments were initiated, proof of concept was shown in rat models, and a patent application was filed. An exclusive license was awarded to Angiotech, a company involved in similar research. Under a subsequent Cooperative Research and Development Agreement (CRADA), NIH and Angiotech were able to successfully demonstrate the invention in a pig model, an excellent model for human cardiovascular treatment. Angiotech was able to partner the basic work in a number of different clinical areas with different partners and eventually sublicensed the lead coronary stent application rights co-exclusively to Cook and Boston Scientific. Boston Scientific later received exclusive worldwide rights for the TAXUS® stents in the field of coronary disease and developed it into a commercial product, while Cook continues with the development of other paclitaxel-eluting products. TAXUS® Express2™ was approved for sale in Europe in January 2003 and in the U.S. in March 2004. The FDA's prior approval of paclitaxel as chemotherapy was critical in facilitating approval of the paclitaxel-stent combination product because the drug's safety was already well established. Market approval was made easier because the stent incorporated the active agent from an approved drug like Taxol® rather than an investigational drug.

These stents are expected to substantially reduce coronary artery bypass surgery, an expensive, highly invasive operation now performed on more than 350,000 Americans a year. In addition, paclitaxel-coated stents are finding their use in peripheral organs such as the colon.

References

1. Gersohn K, "New developments in cardiac stents lead to improved 'keyhole' surgeries", Canadian Healthcare Technology, May 2005.
2. Technology Transfer: NIH-Private Sector Partnership in the Development of Taxol: GAO Report 03-829.

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