Features

ROBODOC – surgical robot success story

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The author

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Abstract

Describes the history of Integrated Surgical Systems (ISS), the US company that created ROBODOC, a surgical robot system used to perform total human hip replacement surgery, and ORTHODOC, a computer workstation that enables orthopaedic surgeons to examine a patient's bone more accurately and perform a pre-operative plan prior to total hip replacement (THR) surgery. ISS recently went public on the NASDAQ Small Cap market. ORTHODOC has received US FDA approval, while ROBODOC's approval is still pending. More than 850 patients in six hospitals worldwide have received surgical procedures performed by ROBODOC.

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Being a pioneer is not always easy. But patience is paying off for Integrated Surgical Systems (ISS), Inc. of Sacramento, California, USA, a company that has created, developed, and successfully brought robotic surgery to the commercial marketplace.

ISS's principal product is the ROBODOC Surgical Assistant System, a computer-controlled surgical robot that, to date, has been used to perform precise total hip-replacement surgical procedures on more than 850 patients worldwide. The first robot to ever perform invasive surgery in the USA, ROBODOC is currently being marketed in Europe, while approval is still pending in the USA.

ROBODOC's history

ROBODOC, the most advanced surgical robotic technology in use today, was envisaged by the late Sacramento veterinarian, Dr Howard "Hap" Paul, and Dr William Bargar, an orthopaedic surgeon. The two surgeons set out in the mid-1980s to find a tool that could carve a cavity in a femur that precisely matched the shape of an artificial hip implant. Traditionally, surgeons use a more primitive method on a patient's leg – a mallet and broach (or rasp) to dig a hole in the thigh bone for the implant. In the early days of hip replacement surgery, implants were affixed in bone using cement. It was discovered, however, that the cement eventually breaks down and many patients have to get replacements in ten or 15 years.

More than 15 per cent of the 750,000 annual hip replacements are repeats. More recently, surgeons have been using cementless implants for many patients. A cementless implant relies on the ingrowth of bone into porous fixation surfaces on the implant, and so the fit of the implant to the cavity is more critical. The goals of Paul and Bargar were to drill a hole so precisely that the implant would make contact with the bone in the areas where ingrowth was desired, and furthermore, to position this cavity accurately in the bone to restore the proper joint biomechanics. Achieving these goals should increase substantially the life of the hip replacement while decreasing the number of repeat replacements.

They took their idea to International Business Machine Corp.'s (IBM) Research Center

Industrial Robot
Volume 24 · Number 3 · 1997 · 231–233

in Yorktown Heights, NY, and formed a joint research project between IBM and the University of California, Davis, in 1986. Later, in 1990, IBM provided the initial funds for a startup company, Integrated Surgical Systems, to commercialize the technology. ISS and IBM jointly developed ROBODOC, a customized version of an industrial robot manufactured by Sankyo Seiki Mfg Co. Ltd, and the Orthodoc Presurgical Planner (ORTHODOC), the computer program that directs its movements. (See Appendix for full chronology of ROBODOC development).

Early success

An earlier version of the ROBODOC System was first used on 26 of Dr Paul's patients, all of which were household dogs with hip injuries. The canine surgeries were all successful. The next step was to perform surgery on human patients and on 7 November 1992, at Sutter General Hospital in Sacramento, California, the first human hip replacement surgery by the ROBODOC tool made its debut on a 64 year old male (see Plate 1). This patient was the first of ten patients in a feasibility study authorized by the US Food and Drug Administration (FDA).

ROBODOC and ORTHODOC revolutionized the current hip replacement procedure. The surgeon places three small locator pins in the patient's femur that serve as guides, providing information on size, shape and orientation of the bone. A computer tomography (CT) scan of the femur is then taken and loaded into the ORTHODOC software. ORTHODOC develops a three-dimensional model of the bone. Using a mouse, the surgeon selects the appropriate implant and places it in the correct position within the bone. The surgeon then creates a tape that contains all the information needed by the robot. The surgical procedure begins by having ROBODOC read the tape from ORTHODOC and perform some diagnostic checks. The surgeon orients the robot to the femur by teaching the positions of the three locator pins and then directs the robot to machine the implant cavity. ROBODOC's machining process takes about 15-25 minutes, depending on the size of the implant. Throughout the entire procedure, the computer screen prompts the surgeon for each step which the surgeon must in turn verify (see Plate 2).

In October 1993, after successful completion of the ten-patient feasibility study, the FDA authorized an expanded programme of up to 300 operations (150 with ROBODOC and 150 in a manual control group). ROBODOC was installed in two US hospitals, New England Baptist in Boston, MA, and Shadyside in Pittsburgh, PA, in addition to the first at Sutter General. Although not part of the FDA authorized study, the system was also installed in Frankfurt, Germany, at the Berufsgenossenschaftliche Unfallklinik (BGU).

Plate 1 The first human hip replacement surgery by ROBODOC is performed at Sutter General Hospital in California

Plate 2 FDA-approved ORTHODOC, computer workstation, a pre-operative surgical planning system, develops a three-dimensional model of the bone

Industrial Robot
Volume 24 · Number 3 · 1997 · 231–233

ROBODOC goes public

Though still waiting for FDA approval to market ROBODOC in the USA, ISS began selling the systems in Europe at the beginning of 1996 at $635,000 each, selling three in Germany that year. As of February 1997, the device has been used on more than 850 patients worldwide. Last November, ISS went public, opening its first day on Wall Street with a share price of $5, and closing at $5.25 on the NASDAQ Small Cap market (NASDAQ:RDOC).

1997 is off to a good start for ISS. Two ROBODOC Surgical Assistant Systems were sold in Austria to AKH, the largest hospital in Austria and the teaching hospital of Vienna University, and to Abteilung am Krankenhaus der Barmherzigen Schwestern, a large, private, Roman Catholic hospital in the city of Linz.

The FDA recently approved ORTHODOC for commercial sale, under a 510(k) notification. "This represents significant progress in our commercialization strategy", said Dr Ramesh Trivedi, president and chief executive officer of ISS.

For more information on the ROBODOC products, contact Integrated Surgical Systems, Inc., 829 West Stadium Lane, Sacramento, California 95834, USA. Tel: 916 646 3487; Fax 916-646-4075.

Appendix: History of ROBODOC

1986:	Drs Paul and Bargar first get idea for ROBODOC
May 1990:	Dr Hap Paul performs first of 26 canine hip replacement surgeries with ROBODOC
November 1990:	ISS formed with $3 million investment from IBM
June 1992:	ISS receives Computerworld/Smithsonian Award in Medicine
November 1992:	First human hip surgery by ROBODOC is performed at Sutter General Hospital
October 1993:	FDA authorizes multicentre clinical study for ROBODOC
August 1994:	First human hip surgery in Europe by ROBODOC
October 1996:	Drs Paul and Bargar receive Joseph F. Engelberger Award
November 1996:	ISS goes public (NASDAQ Small Cap market)
January 1997:	ISS sells two ROBODOC systems in Austria
February 1997:	ORTHODOC receives FDA approval