Robotic Catheter System Efficient, Safe For Vascular Procedures

Hansen Medical, Inc. announces results from a pre-clinical study showing that use of its Sensei@ Robotic Catheter System in procedures for treatment of vascular disease has the potential to reduce procedure time by 80 percent, which may result in a significant reduction in both radiation exposure and catheter manipulations.

In addition, results from the pre-clinical study demonstrate that the robotic system improves operator performance, potentially reducing the risk of dissection or embolization. The pre-clinical study appeared in the April 2010 issue of the Journal of Vascular Surgery.

The pre-clinical study, which took place at Imperial College Healthcare NHS Trust, was performed by a team of 15 clinicians under the guidance of Professor Nick Cheshire and Dr. Celia Riga along with Dr. Colin Bicknell and Dr. Mo Hamady.

The purpose was to investigate whether the endovascular procedure of treating aneurysms using fenestrated endografts can be enhanced by a remotely steerable, robotic endovascular catheter system. The robotic procedure was developed in conjunction with the Department of Biosurgery and Surgical Technology at Imperial College London.

The clinicians investigated the use of the robotic catheter system in a physiologically accurate model. The fenestrated endograft is a device used to treat aortic aneurysms, which is a disease that affects more than one million people in the United States. The study also investigated the ability to simplify some of the most difficult, unpredictable and lengthy steps of the procedure.

"It can be very time consuming to accurately position a stent graft during the treatment of an aneurysm because the process is highly variable and depends on the complexity of the patient's vascular anatomy," said Professor Nick Cheshire, Head of Circulation Sciences and Renal Medicine at the Trust, and Professor of Vascular Surgery at Imperial College London. "The results of our pre-clinical study show that using flexible robotic technology for complex endograft interventions has the potential to greatly improve the safety and efficacy of this procedure due to the dramatic reduction in procedure time and catheter movements, as well as the decreased radiation exposure."

According to Dr. Riga, Academic Clinical Lecturer & Registrar in Vascular Surgery, Department of Biosurgery and Surgical Technology, Imperial College, the study demonstrated several potential benefits of the robotic system for complex endovascular tasks.

"Total procedure times and the number of catheter tip movements were significantly reduced for all operators regardless of their level of endovascular experience," said Dr. Riga. "These results reflect the intuitive nature of this robotic catheter technology developed by Hansen Medical, which has the potential to improve overall procedural safety, whilst allowing more patients to be treated via a minimally invasive endovascular approach."

In the study, robotic cannulation (insertion of a catheter into a branch vessel) for aneurysm repair was significantly faster than standard cannulation using conventional endovascular catheters for all target vessels. In addition, the number of movements at the catheter tip required to complete each task during the procedure was significantly reduced, resulting from the ability to change the shape of the robotic catheter tip quickly, and from increased 3D control of that catheter tip. Overall pre-clinical results showed a 90 percent decrease in catheter manipulations inside the aorta using the Hansen Medical robotic system as compared to manual technique.

Previous clinical studies have shown that catheter manipulation during vascular procedures can result in stroke or embolization of disease in the arteries(1). The results from this pre-clinical study showed a significant reduction in the number of catheter manipulations performed robotically versus manual technique, which could potentially reduce the risk of emboli and other adverse events during vascular procedures.

"We are very encouraged by the results of this study, as it clearly demonstrates what physicians may be able to accomplish when they use Hansen Medical's advanced technology," said Frederic Moll, M.D. (http://www.hansenmedical.com/) , president and chief executive officer of Hansen Medical. "We believe our flexible robotics technology has the potential to take the complexity out of procedures that are challenging to physicians, and, in the future, may enable vascular surgeons to convert their practice from open surgery to non-invasive therapy."

Hansen Medical's flexible robotic technology provides physicians with the ability to precisely manipulate catheters using advanced three-dimensional controls and visualization. Hansen Medical continues to develop and advance flexible robotics technology for applications including vascular and interventional medicine. The Sensei system is approved for use in electrophysiology in the United States, Europe and other countries.

(1) Eskandari et al. 2005, Stroke

About Aneurysm Disease: The aorta is the largest artery in the human body and aneurysm formation can occur anywhere in the aorta. An aneurysm is a localized or diffuse dilatation of an artery with a diameter at least 50 percent greater than the normal size of the artery. This results from weakening and swelling of the artery's walls, often as people age, and is frequently fatal if it ruptures.

Abdominal aortic aneurysms (AAA) are the 13th leading cause of death in the United States. There are over 1.2 million people with AAA in the United States, and

it is estimated that only 180,000, or 15 percent, are diagnosed. Approximately one-third of abdominal aortic aneurysms will rupture if left untreated. According to Millennium Research Group (2009), the number of abdominal and thoracic aneurysm endovascular repairs performed in the United States and in Europe totaled 50,000 and 20,000 respectively.

Procedures to treat complex thoraco-abdominal aneurysm disease include surgery, where the surgeon will make an incision in the chest wall to replace the weakened portion of the aorta, or it can be treated by an endovascular repair, which is a minimally invasive procedure. Stent grafts act as scaffolding that can help prevent the aneurysm from bursting when positioned across the weakened section. This approach is gaining acceptance because of the high morbidity associated with this condition, especially in patients unable to withstand the traditional surgical approach. However, this procedure can be technically challenging for clinicians.

For more information, visit www.hansenmedical.com [1]

Links:
[1] http://www.hansenmedical.com