CASE STUDY

CATHETER DESIGN OPTIMIZATION USING THE EMS SOFTWARE PACKAGE

Japan Lifeline Co., Ltd.

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Norihiko Mitsumune (left), Yuko Tanaka (middle), and Yasuhiro Kojima(right)

"USING THE ELECTROMAGNETIC SOFTWARE PACKAGE EMS, WE DEVELOPED OPTIMAL CATHETERS FASTER AND AT A LOWER COST WITH A MINIMUM NUMBER OF PHYSICAL PROTOTYPES. AS A RESULT, WE BROUGHT OUR PRODUCTS FASTER TO MARKET. WE COULD NOT HAVE DONE WITHOUT EMS"

JLL Japan Lifeline

JAPAN LIFELINE CO., LTD. OVERVIEW

Research Center (Toda)

About Japan lifeline:

Japan Lifeline Co. Ltd. was founded in February 1981. From 1981 to almost 1999, the company was merely a distributor of a cardiovascular medical equipment. Around August 1999, the company opened a new Research and Development center and started to develop its own line of cardiovascular medical devices. Today, Japan Lifeline is a major manufacturer and distributor of cardiovascular equipment and hence striving to improve the quality of life of millions of cardiac patients. The company now has sales offices in 30 locations across the country, in addition to its headquarters in Tokyo. The company's research and development center, where most of its innovative new products are developed, is located in Toda City in the state of Saitama.

SIMULATIONS SOFTWARE PACKAGES AND THE BENCHMARK TEST

KOZO KEIKAKU ENGINEERING and the introduction of the EMS package:

KOZO KEIKAKU ENGINEERING (KKE) has introduced to Japan Lifeline three important design software packages:

1. SolidWorks from SolidWorks Corporation, Boston, USA

SolidWorks is the #1 CAD package, a powerful 3D design solution for rapid creation of parts, assemblies, and 2D drawings (www.solidworks.com).

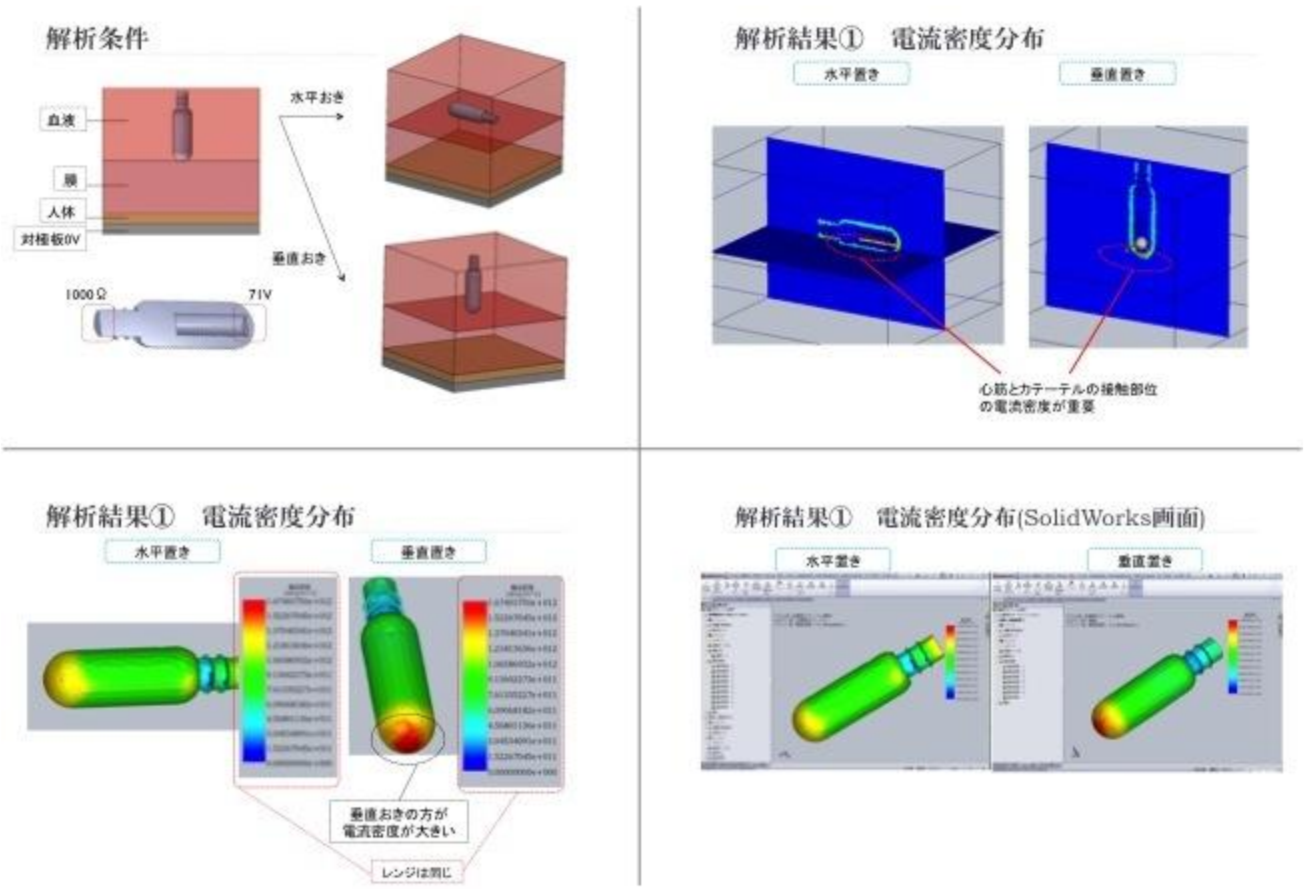
2. EMS from ElectroMagneticWorks Inc., Montreal, Canada

EMS is a 3D electromagnetic field simulator software suite, based on the finite element method. It is fully embedded in SolidWorks and Gold Certified by SolidWorks Corporation (www.emworks.com).

3. SolidWorks Flow Simulation from SolidWorks Corporation, Boston, USA

Flow Simulation simulates fluid flow, heat transfer, and fluid forces. It is also fully embedded in SolidWorks (www.solidworks.com).

Up until May 2012, we primarily relied on experimental techniques in the development and testing of our new catheters. The "trial and error" approach was costly both in terms of time and resources. Starting July 2012, we started testing the analysis software packages introduced to us by KKE. When we compared the experimental and the analysis results on some benchmark catheters, they were consistently matching. Hence, we soon realized the added-value of simulation in general and the above software packages in particular.



Analysis results were consistent with the experiment. It's crucial that the current density and potential distribution be visualized

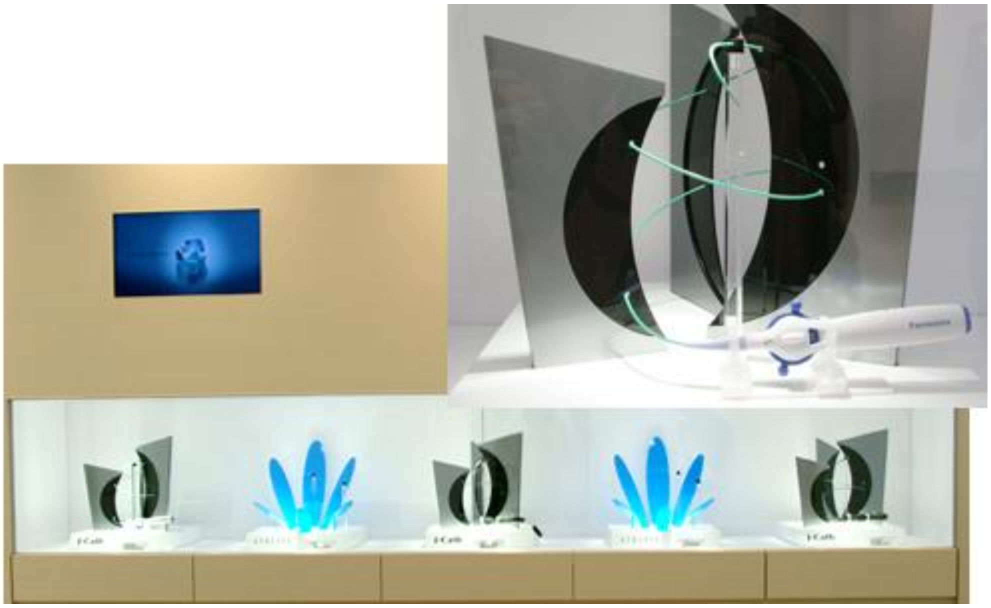
THE REASON WHY JAPAN LIFELINE DEVELOPED ABLATION CATHETERS ON ITS OWN

The type of produced catheters:

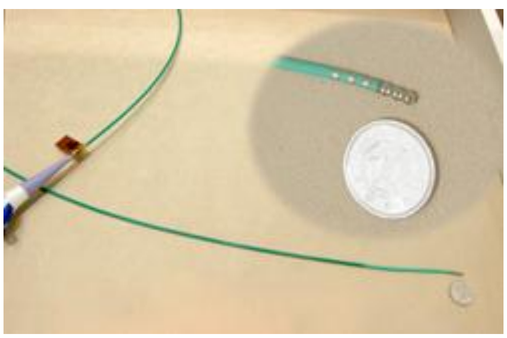
We develop various type of cardiovascular catheters. For instance, we produce the so called Electrophysiology (EP) catheters which are primarily for arrhythmia diagnosis. Another type is the ablation catheter which uses an RF current of 500 KHz to treat the arrhythmia itself. Another important device is the Guided Wire which itself is not a catheter but guides the balloon catheter to the target treatment area.

Reasons behind developing:

First and above all, we want to respond to the need of medical practitioners and their patients. These needs are not necessarily fulfilled by the imported catheters. For instance, a tip of catheter should, as much as possible, follow the movement of the hand of the physician. Furthermore, some types of arrhythmia do not respond to standard catheters, thus the need to develop special purpose devices. To respond to the above needs and special requirements we had to work closely with the physicians and acquire advanced simulation tools such SolidWorks and EMS.



Some of our catheters displayed at the entrance of our research center
Upper right catheter ablation



Display of three ablation catheters

EMS & the catheter design:

Soon after comparing the experimental and the analysis results on some benchmark catheters and realizing the added-value of simulation, we started using EMS in the development of our line of catheters, i.e. around July 2012.
Typically, the ablation catheter with its platinum tip is guided into the patient's heart and placed in contact with the damaged myocardial tissue that causes the re-entry current which is responsible for the cardiac arrhythmias. Once in place, the physician applies an RF current at 500 KHz from a high frequency generator for a period of few milliseconds. When the current reaches the platinum tip the latter heats up to a temperature of at least 45 ^{o}C, which in turn burns the damaged myocardial tissue and stops the re-entry current and hence curing the arrhythmias or the so called tachycardia.
This seemingly simple mechanism requires an accurate modeling of the current in the catheter, the resulting electromagnetic field around the platinum tip as well as its temperature. EMS enabled us to accomplish such tasks in a straight forward manner with an easy to use and intuitive interface, all within the SolidWorks environment.

UTILIZING SIMULATION EXPERIMENTS TO REFINE THE PREVIOUS MODELS

Before using EMS:

Before using EMS, we had to resort to a "trial and error" tedious process that relied heavily on creating multiple prototype of catheters that are inserted in animal heart. To assess the effectiveness of the procedure and the experimental catheter, the animal is then sacrificed and the size of the lesion in the myocardial tissue is measured. Clearly, it was an expensive and time consuming procedure that did not necessarily guarantee the best outcome.

While using EMS:

Simple. We create our "prototype" in SolidWorks in a matter of minutes. We then click on the EMS tab, right inside SolidWorks and create an electro-thermal "study" or "what if scenario". In few minutes we obtain a full range of important design indicator results. That is, we obtain the electric field, the current density, the potential, the temperature, the temperature gradient, and the heat flux in the tissue, blood, and the catheter itself. Furthermore, all of the results can be visualized in various formats such as fringe, vector, contour, section, line, and, clipping plots. The results can easily be zoomed-in, exported, and dissected. If the obtained results are satisfactory, we move to the laboratory and actually build the model. Otherwise, we can easily change various design parameters such as shape, material, and location and simulate again until satisfactory results are obtained. Consequently, we reach our "best design" in a much shorter time with much less resources.

THE EMS EFFECTIVENESS AND OPERABILITY

Yasuhiro Kojima - Development Division Chief

Please tell us a little more about the benefits of using EMS:
The introduction of EMS into our catheter design cycle has a significant impact on three main design issues:

1. EMS made the product development more reliable since it provided an additional validation to the experimental verification. As a matter of fact, the higher is the current density at the catheter tip, the larger is the lesion in the myocardial tissue. However, assessing the size of the lesion is rather tedious and often requires the scarification of an animal. Using EMS, we reached a high level of confidence in predicting the lesion size.
2. EMS made the product development faster and less expensive by cutting on the number of physical prototypes needed. Hence, the product is brought to market much faster which is, in fact, the general trend in recent years for most technological products.
3. Having a powerful post-processor, EMS made the results presentation easier, more compelling, and more effective. One particular post-processing feature that ought to be emphasized is the automatic report generation. This feature captures all input and output in a customizable well-organized report in MS Words, Html, or pdf format. The report can easily be shared with co-workers, managers, and customers. It may as well be included in Power Point presentations or simply saved for future reference.

Mr. Hiroshi Tanaka conidia Development Division

How about the usability of the EMS?
It is above all a fast simulation tool. Furthermore, being an Add-in to SolidWorks is very valuable since it allows the designer to work right within an integrated environment having the same "look and feel" without any need for exporting, importing, healing, or fixing the geometrical data. Consequently, the engineer can concentrate on design and not CAD.

What do you think about the future direction?
After establishing the fact that that EMS practically matches the experimental results, we were sold on the value of simulations. Again, it is the way to bring our products faster to market. However, EMS and other simulation products are still limited in a sense that they "don't learn". When a designer builds a prototype, he or she accumulates a know-how that can correlate the expected outcome to the model itself. To be truly useful, simulation packages should also have a built-in intelligence that "learns" from previous simulation runs. For instance, we are looking forward to seeing capabilities that would predict the myocardial lesions' size for any scenario just by simulating few cases and "learning" from them. If and when that happens, it will be the ultimate joy of a designer.

Lin Zong light 彦氏 Development Division

Interview date: August 2012

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February 6, 1981 Founded
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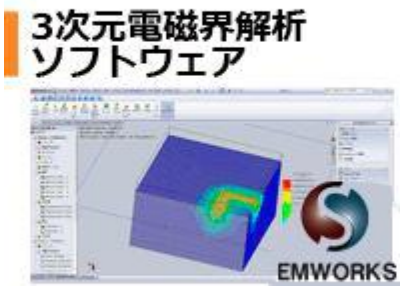
Solutions that are used in this case



EMS from ElectroMagneticWorks Inc., Montreal, Canada
www.emworks.com

SolidWorks from SolidWorks Corporation, Boston, USA
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