Digital Innovation: Software as a Medical Device

Better Insights = Better Outcomes

Executive Summary

A multinational corporation focused on consumer health, pharmaceuticals, and medical devices is providing ground breaking work connecting our digital and physical worlds. They needed help driving innovation in a division focused on advancing Software as a Medical Device (SaMD).

> Software as a Medical Device (SaMD) causing disruption in almost every aspect of the healthcare sector. It's forcing a seismic shift in therapeutics, genomics, drug discovery & development, bioinformatics, robotics, point-of-care (POC) diagnostics. In short, SaMD is changing forever how healthcare is administered and delivered.

The organization needed talent that could help them design, simulate, analyse, and manufacture medical devices using model-based visualization technology overlaid in the real world. Entech delivered a team of talented engineers through its GradTech program. Using innovative software design and next generation tools, Entech resolved technology challenges related to improved bone grafting using Augmented and Virtual Reality (AR/VR). Entech had a direct impact on improved design, strength, and integrity of bone implants scenarios and helping to ensure better patient outcomes.

Challenges

Bone grafting is a surgical procedure that uses transplanted bone to repair and rebuild diseased or damaged bones almost anywhere in your body. The ability to create 3D models of bones and bone grafts for patients using AR and VR holds tremendous potential for reduced surgery risks and improving patient health. Using a virtual environment, bone grafts are exactly matched to bone images to enable extremely accurate manufacturing. This in turn lowers surgical implantation risks for patients. In addition, virtualized surgical practice scenarios are being developed so doctors can

practice in the virtual world and be better prepared for the actual surgical procedure.

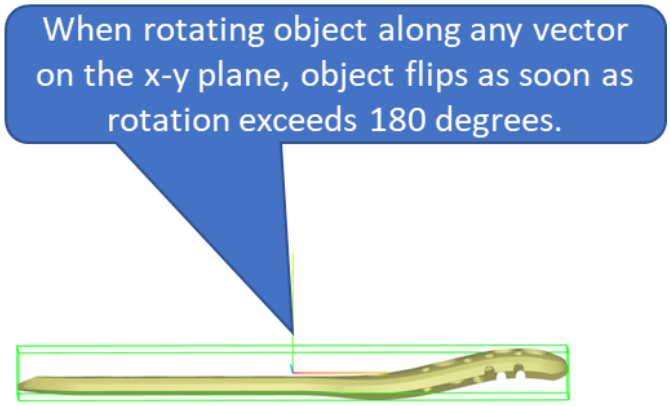
The steps along the way to applying and commercializing this SaMD technology requires development of software and engineering practices and appropriate production and assembly techniques. One of the tools the organization was using for 3D modelling was originally designed for creating video games. While it is a great tool, it was not designed to handle huge graphics libraries of bones and bone graft images. These graphics libraries contain very large files that must be loaded into the system every time the software platform is opened. Because of this, the files were taking a long time to load before engineers could even start their AR/VR simulation work. These long wait times were slowing design and testing and creating a high degree of frustration for engineers trying to do their work. More importantly, the organizations business goal was being hindered. The load time issue was an efficiency drain that would not enable scaling of the bone grafting SaMD to moves into mass production and delivery.

Solution-Virtual Bones

In order to adequately simulate bone grafts for a large population, first the team needed to create a large library of bone images. They scanned real bone images to create a library of virtual bone representations. These virtual bones were imported into the 3D tool the organization was using. The Entech team determined that the load time issue that was hindering progress on the bone graft program was based on the fact that the tool was an application platform that was strongly coupled with traditional Operating System (OS) dynamic link libraries (dll's) and other components, resulting in heavy software architectural overhead. The tool was provided by a third-party vendor, thus changing its architectural design was not an option for fixing the problem. A new approach was required.

GradTech Innovation

GradTech team members from Entech discovered that Three.js, a javascript software library that makes Web Graphics Library (WebGL) easier could perform much of the required 3D modelling that was required without the load-time overhead. Three.js was able to generate 3D models of bone grafts in close to real time. However, when rendering 3D models and rotating them in 3D space using Three.js, a problem called Gimbal Locking was encountered.



Gimble Locking

Gimbal Locking is a known issue that can occur in 3D modelling (It's also a real-world problem with sensors). It means that in certain configurations when rotating an object on an x-y plane in 3D space, the object flips as soon as rotation exceeds 180 degrees. This happens with systems that use math called Euler angles. Without getting too deep into the math, Euler angles is an x, y, z coordinate system for 3D space. The Gimbal Lock problem occurs because an objects position in 3D space cannot be uniquely determined. This can be confusing to understand, but think of it this way. If you start at a single point and make a series of left turns or a series of right turns, you get back to the same point. The system knows you are at the starting point, but doesn't know how you

got there. So, the system gets confused and flips the image. This is not an exact representation of the issue because to truly understand it requires going deep into the math, but hopefully this example gets the point across.

There are mathematical ways around this Gimbal Lock problem that the Entech team had to find and develop software to resolve. The solution uses something called Quaternions. An explanation of Quaternions is out of scope for this paper, but suffice it to say that they provide a convenient mathematical notation for representing orientations and rotations of objects in three dimensions without the Gimbal Lock problem.

Results: Better Health and Business Outcomes

The digital innovation and problem solving described above is just one example of the type of research and development that Entech and Entech's GradTech teams are involved in. The end result of the SaMD scenarios is that the organization now uses a combination of Three.js and their third-party tool for the bone graft virtualization program. Overcoming the image load problem was just one of the hurdles the Entech team has resolved towards producing better outcomes for patients and better business outcomes. This solution has paved-the-way for mass production of improved bone grafting and advanced the state of the art of SaMD.

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