Institution:
University of Cambridge

Unit of Assessment:
UoA15

Title of case study:
Tracked 3-D Ultrasound Imaging for MedaPhor and Schallware

1. Summary of the impact (indicative maximum 100 words)

Research at the University of Cambridge Department of Engineering (DoEng) has enabled accurate positioning to be added to 2D freehand ultrasound probes to enable the acquisition of large coherent blocks of high-resolution 3D ultrasound image data. The software code base developed in the DoEng was licensed to two separate companies, Schallware and MedaPhor, to enable them each to develop an ultrasound training product. Both companies have sold to more than 30 customers worldwide during the REF impact period; the Cambridge software had a key role in contributing to the innovation and quality of the products developed by both companies, and significantly increased the speed at which they were able to bring these products to market.

2. Underpinning research (indicative maximum 500 words)

The underpinning research on 3D ultrasound imaging is founded on the work of the Medical Imaging Group ("the Group") and its three principal members in the University of Cambridge Department of Engineering (DoEng). Professor Richard Prager founded the Medical Imaging Group when he became a Lecturer in the DoEng in 1992 (promoted to Professor in 2008). He started the preliminary research on 3D ultrasound imaging as Principal Investigator for the EPSRC-funded project *"Stradivarius"*, which started in October 1992 and finished in February 1996 (all significant research was conducted from 1993 onwards). Dr Andrew Gee joined the Group as a DoEng Lecturer in 1996 to help lead the EC-funded project, *"Solus-3D"* (Standardisation of On-Line Ultrasound Scanning in 3 Dimensions), which ran from 1996 to 1999 with Prager as the Co-Investigator. Graham Treece was a Research Student in the Group before working as a Research Associate from 2001 on the Group's EPSRC-funded project *"High Definition 3D Ultrasound Imaging"*, which ran from 2000 to 2004 with Prager as the Principal Investigator. Treece was subsequently awarded a prestigious five-year Fellowship by the EPSRC / Royal Academy of Engineering before becoming the first holder of the Evelyn Trust Lectureship in Engineering for Clinical Practice in 2008. These members of the Group, the grants mentioned above and Treece's fellowship created the research outputs described below.

Tracked 3D ultrasound involves using a magnetic or optical tracking device to measure the trajectory of the ultrasound probe while the clinician is scanning. This information can then be combined with the ultrasound images to produce a three-dimensional data set. It is particularly useful where an extended volume needs to be scanned, or in cases when there is a need to register the acquired data to an external coordinate system. The Group began work on the *Stradx* tracked 3D ultrasound software in 1996. In 2004, the Group created a second system called *Stradwin*, offering similar functionality but with a user interface designed for clinicians. Clinical applications were provided through collaboration with the University Department of Radiology at Addenbrooke's Hospital.

The first achievement of the research was to reduce the time for accurate spatial calibration of the acquisition system from half a day to about ten minutes [1,2]. Novel tools were then produced for visualisation [3] and volume measurement [4] of the unstructured data. The Group invented a new "voxel-free" approach to represent data of this sort that resulted in clearer images, more accurate measurements and faster performance [3]. A unique algorithm was created to help mitigate the distortion of acquired data due to the flexibility of human tissue [5], and the overall accuracy of the system was subjected to detailed assessment [6].

The result is a comprehensive system for the acquisition, visualisation and measurement of accurate three-dimensional ultrasound data. Because of the fixed coordinates of the tracking system used to measure the trajectory of the probe, this data can be easily assembled into a large, co-registered, anatomical library.

3. References to the research (indicative maximum of six references)

1.* R. W. Prager, R. N. Rohling, A. H. Gee and L. Berman. Rapid calibration for 3-D freehand ultrasound. Ultrasound in Medicine and Biology, 24(6):855–869, DOI: 10.1016/S0301-5629(98)00044-1, 1998.

2. P-W. Hsu, G. M. Treece, R. W. Prager, N. E. Houghton, and A. H. Gee. Comparison of freehand 3-D ultrasound calibration techniques using a stylus. Ultrasound in Medicine and Biology, 34(10):1610–1621, DOI: 10.1016/j.ultrasmedbio.2008.02.015, October 2008

3.* R. W. Prager, A. H. Gee and L. Berman. Stradx: real-time acquisition and visualization of freehand three-dimensional ultrasound. Medical Image Analysis, 3(2):129–140, DOI: 10.1016/S1361-8415(99)80003-6, 1999.

4. G. M. Treece, R. W. Prager, A. H. Gee and L. Berman. 3D ultrasound measurement of large organ volume. Medical Image Analysis, 5(1):41–54, DOI: 10.1016/S1361-8415(00)00034-7, 2001.

5. G. M. Treece, R. W. Prager, A. H. Gee and L. Berman. Correction of probe pressure artefacts in freehand 3D ultrasound. Medical Image Analysis, 6(3):199-214, DOI: 10.1016/S1361-8415(02)00080-4, 2002.

6.* G. M. Treece, A. H. Gee, R. W. Prager, C. J. C. Cash and L. Berman. High definition freehand 3-D ultrasound. Ultrasound in Medicine and Biology, 29(4):529-546, DOI: 10.1016/S0301-5629(02)00735-4, 2003.

*References which best represent the quality of the underpinning research.

4. Details of the impact (indicative maximum 750 words)

Based on the research described above, Schallware GmbH developed an ultrasound simulator that allows clinicians to practice diagnostic scanning under realistic conditions using a library of normal and pathological cases. A dummy probe is moved over a dummy torso to generate the relevant ultrasound images on the simulator screen, just as would be shown on an ultrasound machine screen for a real scan.

In May 2007, Schallware bought a one-off source-code licence for the DoEng Stradx software, which was arranged through Cambridge Enterprise, to provide a starting point for the development of their product. Stradx provides tools for acquisition, visualisation and measurement of tracked 3D ultrasound, and all of these are important components in the Schallware system. The Schallware General Manager says: *"The benefit of Stradx source was the access to a huge collections of ideas",* and for the development of the Schallware product he says: *"our [i.e. the Schallware] software development started with Stradx source for acquisition and simulation application".* He continues: *"With Stradx source we maybe avoided wrong development paths and could establish in short time a first prototype. About that I am still lucky [sic]." [7]*

Since the start of 2008, Schallware has built up 30 customers in 10 countries including Johns Hopkins University; NAIT, Edmonton, Canada; Zurich University; Erlangen University; and GMC Dubai, UAE. It also has a leasing business with five simulators being used to run about 25 courses annually in universities in Germany, Switzerland, the Netherlands and Belgium. Attendees at these courses include clinicians and staff from pharmaceutical companies such as Merck, Sharp, Novatis and Dohme. The Schallware General Manager, estimates that 2,400 clinicians have been trained in these courses alone (i.e. not counting the 30 customers with their own Schallware system). Revenue from Schallware's 3D ultrasound simulators was EUR250k in 2011 and EUR300k in 2012.

MedaPhor Limited is a supplier of simulator software that integrates with a variety of ultrasound systems to enable sonographer training without the need for a human subject. The training system needs large and comprehensive datasets to provide the breadth of scans that a trainee sonographer needs to practise.

In January 2011, MedaPhor bought a one-off licence through Cambridge Enterprise for the DoEng Stradwin ultrasound acquisition system and software code-base to help it build an accurate three-dimensional ultrasound atlas for their clinical training system, ScanTrainer. Stradwin allows for the rapid acquisition and integration of these datasets into the MedaPhor software. The time taken to produce a single dataset and make it ready for training use is now approximately two weeks as a result of having the volume of high-resolution data and necessary positional information. Before the purchase of Stradwin, the production of such a dataset took in the region of three months.

MedaPhor has specifically stated that spatial calibration, such as that described in reference [1], was key to achieving the required accuracy. As a consequence this was fundamental to their ability to acquire accurate data from multiple patients.

The real-time acquisition and visualisation tools described in reference [3] increased the efficiency of their workflow by enabling the quality and appropriateness of 3D data to be checked immediately after recording.

MedaPhor also use Stradwin for data alignment [5] and volume measurement [4] because Stradwin's algorithms have been designed specifically to address the challenges presented by the structure of 3D ultrasound data. They therefore out-perform other more generic tools.

The Stradwin software has proved to be a flexible platform with a sound architecture that MedaPhor now use as a basis for much of their work. MedaPhor's Chief Technical Officer [8] says that the purchase of Stradwin was a key positive step in the development of the company and they could not have achieved their current success without it. MedaPhor's customers include Birmingham Women's Hospital, St James's University Hospital Leeds, Yale University, the Karolinska Institute (Stockholm) and the Fremantle Institute (Western Australia).

As at April 2013, MedaPhor had sold over 50 units in 9 countries. MedaPhor estimate that, in the UK alone, more than 500 people to date (June 2013) have trained using ScanTrainer during the REF impact period. Revenue from its 3D ultrasound simulators was GBP362k in 2011 and GBP739k in 2012.

The systems provided by both Schallware and MedaPhor enable trainee clinicians to perform clinical ultrasound scans relating to a wide variety of different examination protocols and different pathologies. The trainees gain a breadth of experience together with a quality of objective feedback that would not be possible without these training systems. A Professor at Rigshospitalet, Copenhagen University Hospital, said of the MedaPhor system: *"We are certain that the ScanTrainer will be a great tool for acquiring some of the necessary skills before examining the patients."* [9]

Binary versions of the DoEng software are also available for free-download on the web: Stradx since 1997 and Stradwin since 2004. Both systems are used by a wide variety of academic and commercial research and development organisations. In the last five years, the use of Stradwin as a research tool has been mentioned in 51 publications with no co-authors from the Cambridge group. For instance, a lecturer at the University of Queensland used Stradwin as a tool in his work and stated: "*We routinely use Stradwin in our research laboratory as a tool for measuring structural properties of muscle and tendon in applied clinical research. Stradwin is not only a stable platform for undertaking freehand 3D ultrasound measurements, but it provides us with all of the advanced analysis tools we require, including volume reconstruction and quantification, 3D length measurements, re-slicing to examine multiple planes and more recently 3D elastography. For example, in 2009, we used it to compare medial gastrocnemius muscle volume, physiological cross-sectional area (PCSA), muscle length, fascicle length, and pennation angle in children aged 2 to 5 years with spastic cerebral palsy (CP) and in typically developing children…3D ultrasound and the Stradwin software allowed us to make scans to children's muscles in seconds and therefore meant that children did not have to be sedated, as would have been the case for other imaging modalities such as magnetic resonance imaging (MRI). The work showed the need for early intervention in order to minimize loss of muscle PCSA in spastic CP. This insight has provided valuable feedback to staff treating children at the Hugh Williamson Gait Analysis Laboratory, the Royal Children's Hospital, Melbourne. This work also resulted in a high-quality publication in Developmental Medicine & Child Neurology in 2011 and makes this data available to hospitals around the world. A further study (2009) has showed the effects of Botulinum Toxin (Botox) injections on muscle development in these young children with CP…and has prompted a new randomised controlled trial at Royal Children's Hospital in Brisbane to determine whether Botox injections may have a deleterious effect on muscle development. We have 4 similar examples from our work since 2008 that have resulted in publications in high-quality journals. The provision of this software has had a significant effect on the speed and quality of our efforts and their translation to clinical practice. Many other collaborators in our field, both academic and clinical, now also use*

Stradwin as the standard foundation for their work." [10]

5. Sources to corroborate the impact (indicative maximum of 10 references)

7. Statement received from General Manager, Schallware GmbH

8. Chief Technical Officer, MedaPhor

9. Professor at Rigshospitalet, Copenhagen University Hospital, http://www.medaphor.com/scantrainer/what-our-customers-say-about-us/testimonials/

10.Statement received from Lecturer in Exercise and Sports Science, University of Queensland