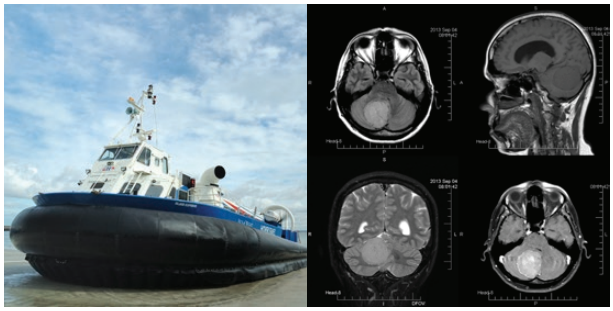
Burn Assessment and what links Moor Instruments and the hovercraft

As part of the celebration of our 30th year in business, we are producing a series of four articles to document key milestones in our history. The first article focussed on how laser Doppler monitoring was a founding product for our business and still plays a key role today (and can be found on our website). In this, the second article, we focus on how the accuracy of burn assessment has been improved by applying non-contact laser Doppler imaging technology to the benefit of patients and clinicians alike.

Newcastle and BTG

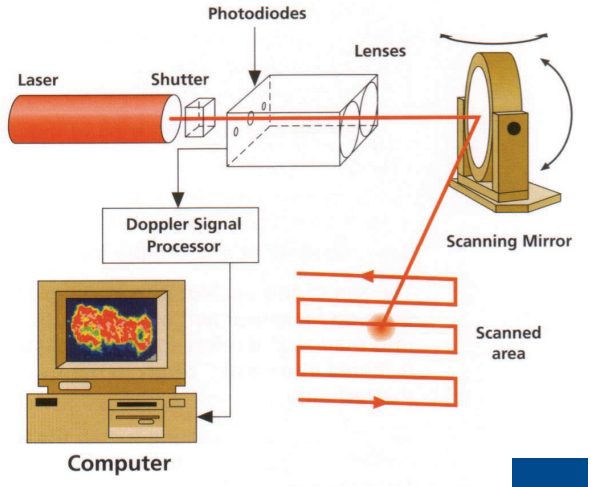
The history of Burn Assessment at Moor starts in 1996 when we were approached by Tim Essex and Philip Byrne of Newcastle University who had developed and patented a unique laser Doppler imaging technique to provide colour coded images of blood flow in the microvasculature. Although there was another commercially available system from Sweden (for which we were the UK distributor), the Newcastle system used a continuously moving beam which offered much faster, high resolution scans and critically a genuine large area capability of up to 50 x 50cm. It used a unique optical design which enabled use in a normally lit environment. In essence it was the first “useable” laser Doppler imager albeit in a working prototype form (that worked exceptionally well!). Tim and Philip had partnered with the British Technology Group to seek a commercial partner. The BTG have a long history of aiding commercialisation of inventive academic research having triumphed in (to name a couple) commercialisation of MRI and patent defence of the hovercraft - successfully defending the UK patent against The Pentagon in Congress. BTG currently hold a very diverse array of ~8000 patents…



Having commercial and technical experience and customer feedback of the Swedish system, we decided to break ties there and move forward with further developing and commercialising the vastly superior Newcastle system signing an agreement in 1995 with BTG. It is worth noting that this system (albeit in a grandchild form) is still available from us today and forms a key part of our imaging portfolio. The system uses a single laser beam (like a laser pointer) moving across the tissue continuously rather than in a stepped fashion making the scanning much more rapid without compromising accuracy.

Early Evidence and Market Research

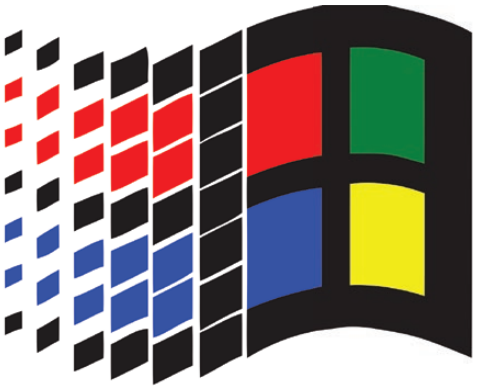
As part of the due diligence process, we were given access to a number of test images taken at Newcastle hospital together with scientific publications. One of the publications applied the LDI technique to burn assessment and whilst the study was small (10 patients) it was a significant indication for us of how the technique could be developed into a clinically useful tool. This publication proved to be “the acorn moment”.



Further research showed that at this time, how you were treated as a burn victim largely relied on the clinical experience and eyes of the surgeon. However, even the best surgeons were honest that, at times, in the more difficult cases, accurate diagnosis was incredibly difficult. In those cases, the standard procedure would be to wait and see how the burn healed (or not) to decide whether a burn should be grafted or not waiting maybe, upwards of two weeks. It seemed somehow as if burn victims had been left behind in hospital diagnostics at a time when it would be unthinkable not to have an X-ray for a broken bone, or an ultrasound scan if pregnant. Thus, we resolved to produce a system that would aid the burn surgeon with more accurate diagnosis and as early as possible after the burn to minimise time to surgery if needed. Thus the Newcastle publication, and this prototype, came together at the right time for us to embark on what would become a major investment project to help revolutionise patient care aiming to make burn assessment much less subjective and more consistent.

Development and Commercial Realisation

Whilst the Newcastle prototype was working (and could scan a patient across a room!), it was large and wall mounted. Our designers focussed on making the system smaller and more mobile, without compromising performance. To put the time scale in context, we eventually launched the first system with brand new control and analysis software on the new Windows 3.1 platform at a time when the Swedish system was still using the MS DOS environment.



Early Adoption

Without ignoring other research applications (spoiler alert - more in Article 3!) we started to attend Burn Congresses routinely – The British Burn Association, European Burn Association, American Burn Association and the Australia and New Zealand Burn Association for example. Interest in the system was keen as it was recognised by Burn Surgeons that there was nothing else other than experience to aid diagnosis in the more difficult cases. Critically important relationships formed at this stage with leaders in the field endure today and include groups such as Newcastle, Gent, Washington, Sydney amongst others too numerous to mention (but essentially a Who's Who of burn specialists).

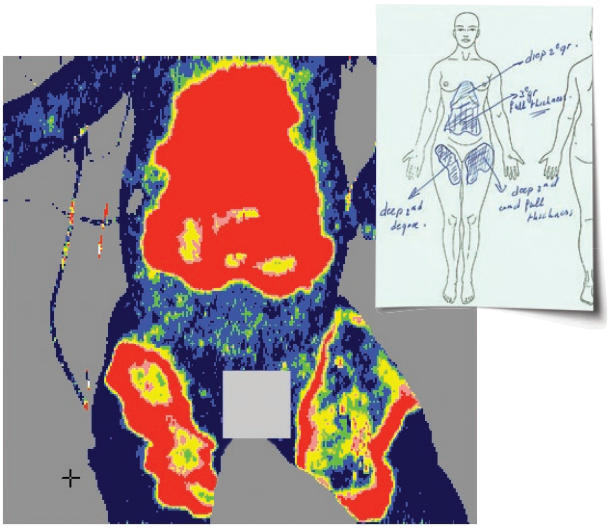
Early adopters used our standard research software and hardware but we quickly realised this couldn't be the final solution that would gain widespread use as we received more feedback.

In order to offer a system that could be used easily and safely in theatre and bedside, we refined the moorLDI into moorLDI2 which featured a sealed "through window" design for ultimate patient safety and a digital camera for colour photograph of the burn. This enabled us to compete for, and win a DTI Government SMART award in 2001 to develop the technique and embark on a multi centre clinical trial to further refine the software and hardware.

Burn Classification and the Concept of Healing Potential

At this time, the traditional burn depth classification system (1st, 2nd, 3rd degree) was challenged as the leading centres we were working with were also using innovative treatments that could alter whether a burn that would have been treated with surgery could be treated without. “Predicted Healing Time” became the diagnosis of choice and working with imminent statisticians, we developed a unique colour palette that gave just that. Scan the burn and get a colour coded map, the colours of which predict how long the burn will take to heal allowing the surgeon to choose the treatment plan based on what was available to the consultant. Importantly, it was shown that the diagnostic accuracy could be improved from 50% - 70% to >95% (together with the clinicians opinion) from just two days post burn, a time when visual indications of burn outcome are notoriously difficult otherwise.

Together with hardware changes, the new software really was the heart of our new MK II clinical tool.



“Diagnostic image of young infant with three burn areas most of which was predicted to heal without surgery by LDI, contrary to clinical opinion”

Adoption of the new MK II system started most notably in the UK and in Australia (with the help of our long term distributor, SDR Technology, based in Sydney), where today (along with the UK) the vast majority of Burn units are equipped with our systems. It should not be underestimated the importance our key opinion leaders had in presenting their findings using the new system on a global platform, spreading the word and helping uptake.

Clinical Trial #1, FDA and NICE

It became apparent that although we were convinced of the benefits, only clinical trials would prove the clinical pedigree we needed. Around 2007, the evaluation of our first five year multi-centre clinical trial came to fruition with our own in-house clinical specialists working alongside key centres in Newcastle, Gent, Baltimore and Washington. Help with the statistical analysis came from UK researcher Rose Baker and the technical skill of in-house software and hardware designers helped bring together a step change in patient diagnosis the system becoming the first ever (and still the only), CE registered (European) and FDA 510k registered (USA) diagnostic system for clinical burn assessment – an important milestone!

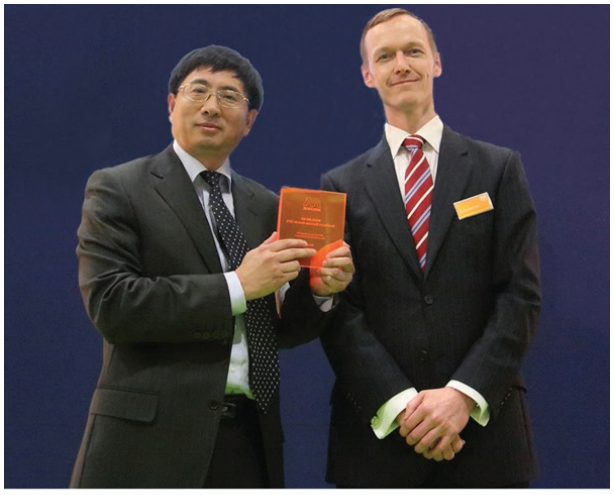
Simultaneously, we wanted to seek independent verification that implementation of our technique was both clinically and cost beneficial so we worked with the National Institute of Health and Care Excellence, a UK Government body whose remit is to evaluate claims made by equipment and drug suppliers and make informed recommendations to the NHS, our UK Government health system. After evaluation, we received the verdict that it did make financial sense to implement the technology alongside the patient benefits on offer.

moorLDLS Line Scanner, Clinical Trial #2 and Medilink Award

Back at Moor though, software and hardware development continued ceaselessly and we patented a new imaging system which would become the moorLDLS-BI. We had recognised that not all burns were large and that not all patients could stay still for long enough to obtain a clear scan (children and the elderly). Thus the new system was intended to target that issue. Rather than using a single beam, the new system used a line projected onto the tissue to sweep quickly across, taking just four seconds to generate an image. A second multi-centre clinical trial in Gent, Sydney, Birmingham, and Dayton was completed in 2013 to establish clinical equivalence between the moorLDI2-BI and the moorLDLS-BI and subsequently the NICE recommendation was modified

to include the new imager. The software had evolved considerably and we now offered our unique colour palette in all versions of burn software, a patient database, DICOM compatibility and a multi-lingual, user friendly design.

In 2014 we were proud to be awarded the Medilink “outstanding achievement” award recognising that “Over the past decade, they (Moor Instruments) have advanced laser Doppler imaging technology from a purely research tool in to a dedicated medical device for burn assessments in clinical settings”.



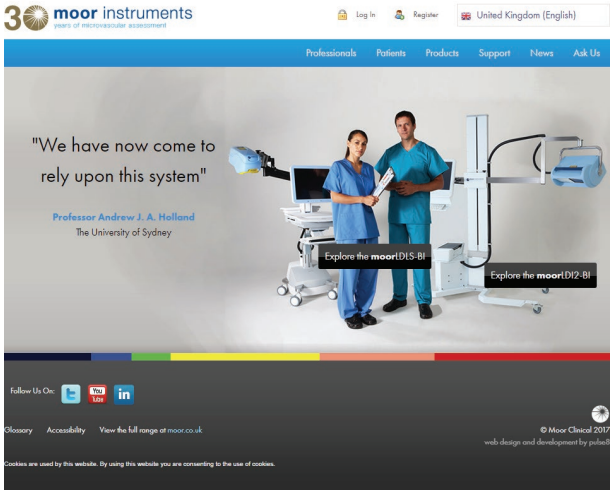
MEDILINK UK

WINNER

OUTSTANDING ACHIEVEMENT

Today and The Future

Today, we offer both systems, the moorLDI2-BI, large area imaging typically for adults and the moorLDLS, rapid imaging for paediatric centres. We supply both directly and through a network of distributors globally (including sister companies in the US and Germany). We have cemented our position as the ONLY global providers of diagnostic burn imagers that have clinical and scientific pedigree, backed by appropriate certification in major markets for clinical diagnosis. We also launched a website dedicated to clinicians and patients alike (www.moorclinical.com)



Uptake of the unit has been solid and our global reach is spreading. Our aim is that every burn victim will ultimately have access to the diagnosis and it has been a source of great pride that we have been able to step in and assist at critical times – our systems helped victims of the Bali bombings for example and more recently the Bucharest nightclub fire. We support and are in admiration of a number of centres and charities, including a close association with Dans Fund for Burns whom we are happy to provide a platform for at the British Burn Association each year.

Burn Assessment imaging has been a defining project for us and we will continue to devote our time to further improvements but, it is by no means our whole imaging story. Our next article will focus on other applications and imagers and how their availability is contributing to research into stroke, wound healing, tumour suppression and stem cell therapies.

As always, if you have any questions about this article, please feel free to contact us!

References

"A new medical instrument is presented that produces a doppler blood flow image from a laser beam in a raster pattern and the results of a pilot study which shows this technique to be highly accurate in assessing burn depth is described."

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"We have devised a new colour palette for LDI burn imaging based on healing times of a series of burns."

Pape, S.A. Baker, R. D. Wilson, D. Hoeksema, H. Jeng, J.C. Spence, R.J. Monstrey, S (2011) Burn wound healing time assessed by laser Doppler imaging (LDI). Part 1: Derivation of a dedicated colour code for image interpretation **Burns.** 38 (2) p187-194.

"LDI can be used in a standardised way as a valid tool for improving on clinical assessment of burn wounds. This can enable earlier appropriate management."

Monstrey, S M. Hoeksema, H. Baker, R D. Jeng, J. Spence, R J. Wilson, D. Pape, S A. (2011) Burn wound healing time assessed by laser Doppler imaging. Part 2: Validation of a dedicated colour code for image interpretation. **Burns.** 37 (2) p249-256.

"The high accuracy of the new line-scan imager was comparable to that of the traditional LDI. Its size and mobility enabled easier ward and outpatient use. The higher scan speed was particularly beneficial for scans in paediatric patients."

Hoeksema H., Baker R.D., Holland A.J.A., Perry T., Jeffery S.L.A., Verbelen J.F., Monstrey S. 2014. A new, fast LDI for assessment of burns: A multi-centre clinical evaluation. **Burns**, Vol 40, pp 1274-1282.

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