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# A collaboration leading to the introduction of an innovative medical device to the international market

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## Abstract

*Development of a medical device is a multi-disciplinary activity. This is particularly the case for laser-based instruments which encompass mechanical, optical, hardware, and software sub-systems, together with the essential industrial design process. In this field, as in many others, small companies are highly innovative. However, the broad range of expertise needed to realise any innovation can be beyond the company's finite resource base. This can lead to extended time scales resulting in lost market opportunity. Financial constraints also make it difficult to use commercial consultancy services. Collaboration with an academic institution can assist in overcoming this dilemma. This process is not without its difficulties and challenges, since it bridges two cultures. However, if approached in an innovative and imaginative way, results can be achieved that are of mutual benefit. The paper reviews the challenges that were faced, the difficulties that were encountered and how these were addressed and managed, to the mutual benefit of both the academic and the industrial partners.*

**Keywords:** innovation, industrial design, collaboration, medical technology, product development, optoelectronics

Vascular birthmarks afflict 0.3% of the population. They are sometimes referred to unkindly as Port-Wine Stains (PWS) and can have a major impact on the quality of life of the individual (Jacobs and Walton, 1976). Until relatively recently no acceptable treatment existed for the removal of these lesions. In the early 1990s a technology emerged from the USA that could treat these lesions effectively (Anderson and Parish, 1983). However, the new laser-based technology proved to be too expensive for the UK's National Health Service. A small company, SLS Ltd, specialising in laser technology, was approached by the NHS and asked if it could develop a device for the treatment of these vascular lesions.

The market for such a product is limited but the benefits to individuals are very significant. The technology is complex and multi-disciplinary. Such a laser system is based upon sophisticated optical, mechanical, chemical, fluid, hardware, and software technology. In addition, the industrial design aspects play an important role particularly since the instrument is used in an environment where the interaction between surgeon and patient

needs to be managed sympathetically. Often the patients are children who are naturally intimidated by the scenario particularly in the light of the medical problem they face.

Few small and medium-sized enterprises (SMEs) would have the necessary resource base to address such a multi-disciplinary project. SLS was no exception and decided to collaborate on aspects of the project with the Centre of Expertise in Optoelectronics at Swansea Institute.

Two aspects of the project were undertaken in collaboration. First the industrial design of the instrument. A team comprising academics and representatives of the SME undertook this sub-project activity. The industrial design was the responsibility of the academic project leader. The SME employed no industrial designers but needed to ensure that the design did not wander outside the boundaries of the initial specification.

The second activity undertaken by the partnership was theoretical modelling of laser tissue interaction. This was necessary to

maximise the therapeutic benefit of the instrument whilst minimising side effects (Van Gemert *et al*, 1991). In this case the SME had only an emerging knowledge of computer modelling and needed the support of an expert in the field. Again, the specification for the problem to be addressed was defined by the SME.

### The Industrial Design

A refreshing side to this project was the integration of specialist industrial designers into the preliminary research phase. The early involvement of key industrial design personnel from the academic partner resulted in a far more open dialogue and exchange of ideas. The role of the designers was to act as initiators in terms of human factors, interface design, establishing the product's architecture and its form. The academic benefits were significant. Academics acting as industrial design consultants were able to feed valuable lessons into curriculum development. Students benefited from increased contact with industrialists and through direct involvement, at MSc level, with live projects. From the industrial design perspective, the industrial collaboration led to major tangible benefits not least in reinforcing the department's philosophy of designing the 'total product'. The contribution to the design pedagogy can only be estimated but repeated success in the last three consecutive Welsh Development Agency technology awards is a valuable indicator. The importance of such collaborative arrangements can be summed up in the words of the Rt. Hon. Tony Blair MP, Prime Minister, 'our success depends on how well we exploit our most valuable assets: our knowledge, skills, and creativity. These are the key to designing high-value goods and services and advanced business practices. They are at the heart of a modern, knowledge driven economy' (Blair, 1998).

### Theoretical Modelling

In order to optimise the laser parameters used for the treatment of PWS, a computer model was developed by a team consisting of the academic partner, laser technologists from the industrial entity, and medical specialists in the field, the academic partner in this case being



Figure 1 Resolved industrial design product – Chromos 585

an expert on theoretical modelling of complex interactions who had worked in this field for a number of years.

The computer model was used to determine how the laser light reacted with the skin and blood vessels within the PWS, and what impact a variation in the light parameters could have on the treatment outcome. This highly complex model was used prior to clinical work being undertaken and greatly reduced the range of possible laser parameters that were available for investigation.

### Conclusions and Discussions

Such a project, undertaken in collaboration between industry and academia faces many challenges. It is argued that enhancing academic/industrial collaboration in near market research could have a meaningful impact on GDP. A region like Wales, for example, is over-dependent on inward investment and has a poor track record of exploiting indigenous R&D. The project which

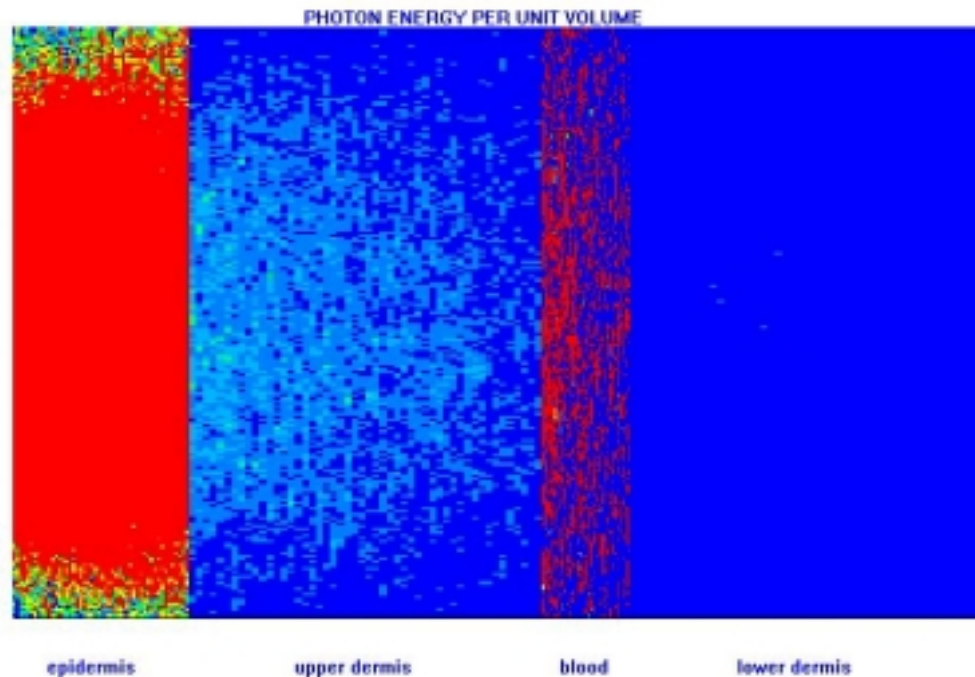


Figure 2 Shows how the light incident on the skin surface is distributed below the surface, this data being used to generate a thermal profile within the Port-Wine Stain.

is the subject of this paper faced many of the standard problems but, in the view of the authors, overcame these leading to benefits to the partners and particularly to the treatment of a very large number of patients.

The major challenges faced were:

- Project management: the management of the timescales and deliverables particularly in the context of academic participants who

have a range of demands on their time, many of those perceived as a higher priority by their line managers.

- Management of perception: the mutual benefits to both partners can be significant. However, dissemination of information to the partner organisations needs to be managed carefully. If colleagues are not kept appropriately informed then a number of problems may emerge such as



Figure 3 Show a typical treatment outcome using the laser parameters predicted by the computer model

- jealousy among academic colleagues who may have a perception that a colleague is receiving financial benefits whilst 'not pulling his weight' in the department.
- a view held by industrial colleagues that a project is taking longer because of the involvement of an academic partner.
- Dissemination of information: the partners may have differing views regarding the appropriate time and way in which to publish results. The industrialist may wish to protect Intellectual Property and keep information 'close to the chest' until the appropriate time. The academic on the other hand may wish to publish at the earliest opportunity.
- Confidentiality: academic institutions are not designed to keep information secret. In fact the opposite is the case: they are institutions, where in general, information should be disseminated. However, in industrial collaboration of this type confidentiality is paramount since it is the only way of securing a market lead.

The benefits to the partners from a well managed project are many and varied and are as follows:

- To the Academic Institution:
  - Income generation: clearly this needs to be agreed on a case-by-case basis. However, financial benefits to the HE institution can be significant,
  - Research support: projects can lead to PhD registration, journal publications and conference presentations. This particular project led to 4 PhD theses and to patents and publications in the learned literature.
  - Student projects: one of the spin-offs from such collaboration is the generation of student projects at undergraduate and postgraduate level. In this case, over 15 MSc projects were generated.
  - Student placements: at undergraduate and postgraduate level.
  - Course development: employees from the company assisted in the

development and validation of a number of new and innovative programmes.

- Profile and publicity: newspaper and television publicity.
- To the industrialist:
  - Access to a range of physical resources that could not normally be afforded by an SME.
  - Access to a broad base of skills that are not normally available in an SME.
  - Access to project specific skills for limited period so avoiding major capital investment and short-term appointments.
  - The opportunity to undertake speculative projects that would not normally be a priority.
  - The ability to test potential employees.

However, the need to carefully project manage academic/industrial collaboration is paramount. The pitfalls should be carefully understood from the outset and the risks defined. The issues that should be considered from day one are:

- 1 Intellectual Property: it is not unusual for individuals in an HEI to have a limited understanding of IPR issues. This, however, can be a major source of conflict. The following should be resolved at the outset:
  - a Ownership
  - b Benefits, including any sharing if appropriate
  - c Funding
  - d Strategy, including territorial issues.
- 2 Timescales and Deliverables: These issues should be discussed and documented.
- 3 Confidentiality: The need to keep project information on a 'needs to know' basis only. Often security at an HEI can leave much to be desired.
- 4 Information Release: A publication strategy should be agreed.
- 5 Documentation: All agreements should be recorded. All levels of the organisations should be informed appropriately. This is essential to avoid future complications.

Not all of these issues were discussed in sufficient detail in advance while undertaking this project. Several unnecessary problems

were therefore encountered during the project. These were largely resolved, leading to a successful outcome. The challenges encountered were ironically not technical or design in nature but political. The recommendation of the authors is therefore that time should be taken to manage the expectation of the partners and to ensure regular written reporting.

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