A REVIEW OF FEA TECHNOLOGY ISSUES CONFRONTING THE BIOMECHANICS INDUSTRY

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SUMMARY

Through the life of the FENET project support of the biomedical area has been patchy, ranging from well supported at the initial meeting at Wiesbaden, to later meetings where, few, if any attendees expressed any interest in the field. (In fact interest is not the correct word – there has never been a shortage of interest, but attendees who earn their living in the field and are prepared to contribute to a session have been thin on the ground) This document aims to draw conclusions from the technical aspects uncovered by FENET, whilst also discussing some of the reasons for the lack of connection between the mainstream FEA world and the Biomedical FEA arena.

1: INITIAL TECHNICAL DEFINITIONS AND AREAS OF INTEREST

Biomedical simulations are many and varied, and cover all simulation disciplines, from the traditional structural analysis to fluid flow, multi-body dynamics and electromagnetics. In some areas, such as the development of replacement joints (arthroplasty), the application of finite element analysis has much in common with other areas such as automotive or aerospace, and the business drivers are much the same. Other areas, specifically pure research, use finite element analysis as a tool to investigate the governing processes and phenomena occurring in the body, and these studies often have little in common with other more traditional pieces of work, be it in technical outlook or business considerations. For this reason summing up the application of simulation techniques in this industry area can appear confusing and at best unfocused, however this is the natural result of an industry dominated by non-engineers and without a regulatory framework in the normal sense.
Initially the following areas were identified as being representative of the interests of the FENET membership

- Joint Replacement and other structural devices
- Heart Valve and other "fluid system" implant devices
- Assessment of environmental influences on the human body, impacts, electromagnetic fields etc
- External support, monitoring and imaging equipment
- Modelling of "pure" bio-processes and structures

In common with the other FENET industry sectors technology readiness levels have been defined, however the fall off of interest meant that the TRL's did not evolve through the lifetime of the project.

2: JOINT REPLACEMENT AND OTHER STRUCTURAL DEVICES

The nature of the joint replacement process means that there is no easy access to implanted devices for servicing – the planned design life of implants is measured in years, 15 years being expected from a hip replacement, and premature component failure is both costly and a burden to health services. As biomedical devices are used in human subjects the scope for testing programs with the aim of product development is somewhat limited, and therefore before first implanting the chances of product failure must be vastly reduced.

The classic application of finite element techniques in Biomedical engineering is in the design of prosthetic hip joints (although the hip joint is the most often used example many other joints are also the subject of replacement because of arthritis; knees, elbows, shoulders and fingers are all routinely replaced). Much work in this field has been conducted at a design level, simple models of the prosthesis attributed basic constraint and load definitions. The complex shape of most prostheses means that the widespread application of FE could only occur when 3D automeshers became available. Although the benefits of this approach over not using analysis at all are obvious the simulation of the actual behaviour of implant in-vivo requires a much more rigorous approach. The current state of the art sees this multi-facet issue addressed.

The simulation of prosthetic joints in-vivo has a number of complex areas. The loads applied to the joint are complex in both spatial and temporal distribution, and much work is currently underway to improve the definition of these and their application to finite element. The actual loading data has been obtained in a number of ways, specifically multi-body dynamics models of the lower limbs and the use of instrumented prosthses, themselves the subject of extensive finite element analysis in the design process (in this case used to improve the response of the internal loadcells). Multi-body dynamics simulations take 2 forms in biomedical applications, those coded specifically for the purpose and others utilising commercial codes such as Adams.

Significant effort is being expended investigating the behaviour of the prosthetic/bone interface. This interface, including polymeric cement or a simple bone/metal interface, is crucial to the success of the implant, loosening and migration of the joint being a significant cause of failure. From a finite element perspective this problem is not straightforward to model. The interface is either in a bonded state or is free slide, with the obvious effects of friction, and modelling the small amounts of relative movement is a challenge in a finite element program. The interface area does not exist in isolation and the modelling of the bone structure adjacent to the implant, and in general, has a great bearing on the quality of analysis carried out. Bone is a complex material system, whose properties vary in almost every way possible – structural properties are anisotropic, heterogeneous, and both age and load rate dependent. Bone is a cellular solid, the interstices being full of liquid, so the variable ratio of solid/liquid across each bone makes for a complex problem to define. Some work is beginning to be published in which the fluid flow velocity and its interaction with the solid phase is considered. Those working in the field have long been aware of these issues and great efforts have been made to capture these effects in finite element models of prosthetics in-vivo, however it is fair to say that a "complete" consideration of all aspects of bone response is still some way off.

Whilst loosening of the prosthesis is a common problem, it is not the only one which causes premature failure of implanted devices. Wear is a significant problem, and again finite element techniques have been used to investigate these. Wear is a result of many factors, but contact mechanics have been modelled in many types of implant, work on modelling the contact force distribution being presented at the FENET meeting in Wiesbaden. In the case of wear prediction loading data is again of critical importance and far from being trivial to apply or obtain.

Apart from joint replacement there are numerous structural implants – the correction of spinal deformity is undertaken using spinal fixators and these are often the subject of finite element analysis studies. As with joint replacements these are often relatively simple devices in a complex environment, and again significant effort has gone into modelling section of the spine to provide an accurate assessment of how the device functions. Work presented at Wiesbaden covered these issues.

Relevant Technology readiness levels

- Enhanced contact algorithms for in prosthesis/bone/cement interface modeling TRL4-7
- Failure indices for bio-materials TRL 1-4
- Bio-specific material models TRL 1-4
- True multi-physics representations for bone/fluid interaction on a micro level TRL 4-8

3: HEART VALVE AND OTHER "FLUID SYSTEM" IMPLANT DEVICES

Prosthetic heart valves have made a significant contribution to the treatment of patients suffering from heart disease, and the requirement for low rates of component failure is probably more marked for these products than in orthopaedic circles. Component failure in heart valves is life threatening.

There are many issues which arise in the design of artificial heart valves which are not immediately obvious. Bio-computability is essential and therefore some novel approaches have been adopted – porcine tissue is used (work on this was presented at Wiesbaden) and material models developed which reflect this. This is not trivial and much work is required in the validation of these material models.

The flow regime in implanted devices is of critical importance, dead areas (from a flow view point) result in blood coagulation and is problematical for the patient. CFD studies have long been carried out to establish and then optimise the flow characteristics of these devices, however a topic of debate concerns how important fluid structural coupling is in these instances. Certainly when compliant valve elements are used there are there are strong arguments for such coupling to be properly recognised.

This is a technology area in which the emerging field of multiphysics simulations has an important role to play, and through the lifetime of the project the technology readiness of the actual solution technology had advanced significantly. However the FENET member who presented this work at the initial meeting did not do further work in this field and in fact did not attend further meetings. This critical issue is developed further in this document, as it is evident that advances in software technology are not reflected in usage by FENET members, or its seems anecdotally, in the biomedical analysis community.

Relevant Technology readiness levels

- Failure indices for bio-materials TRL 1-4
- Bio-specific material models TRL 1-4
- True multi-physics representations for soft tissue fluid interaction on a micro level TRL 4-8

4: ENVIRONMENTAL INFLUENCES

This category covers the assessment of impact on the human body – principally driven by improved safety standards for cars, and sundry other effects such as electromagnetic radiation.

Death and injury associated with road traffic accidents has a vast cost to society as a whole and therefore any steps taken to reduce of eliminate this will have a significant return. There are a number of options for testing occupant safety and hence developing new and more efficient motor vehicles. These are crash test dummy testing, cadaveric testing, live occupant testing and computer modelling. Each of these approaches has drawbacks, none apart from live occupant testing offering a fully representative model, however computer modelling techniques are reaching the stage where FE models can be used to predict injury levels.

In this area extensive work has been carried out into bio-mimetic models of the human form which enhance the understanding of injury mechanisms in crash scenarios. As usual, once an acceptable model has been developed this can then be used to optimise the design of new and safer automotive environments.

Models used in crash modelling are generally complex and take account of soft tissue and fluid regions, in fact fluid closely coupled fluid structural models will have a real part to play in the development of this technology. Models shown at the Wiesbaden meeting included a torso used to investigate the impact of the human body with a steering wheel in an impact scenario, a head model again used in impact studies and a foot /ankle/leg model. A UK centric view of automotive crash test predictions is one of decline, following the very real decline of the UK automotive industry

Relevant Technology readiness levels

- Fluid Structural coupling for macro structures - organs/chest cavity brain/brain cavity TRL 4-8

5: STATE OF THE MARKET

Industry Drivers

The predominant industry drivers are different for each specific area of the industry, however the reduction of in service failure can be seen as universal. The direct gearing of simulation to reduced in service failure is less evident than perhaps is evident in areas such as automotive, as the failure modes of implants are not generally a result of straightforward component failure, but much more likely to be failure of interfaces, or even the surrounding bone structure. The simulation of these effects is at a much lower trl than the modelling of failure in metallic structures.

Reduction of time to market was suggested as an industry driver at a FENET discussion session, however this is a real "motherhood and apple pie" issue; no-one was arguing that increased times to market are a business benefit. Little evidence was presented for using analysis to really reduce time to market, as seen in other industries, so this point is not left with any great weight.

Other recognised industry drivers include the research of bio-processes through simulation, for example the understanding of bone growth and its relationship to developmental problems such as scoliosis, and the understanding of injury mechanisms.

In the course of the FENET workshops other factors were highlighted, and these included FDA approval, virtual surgery and the increased usage of sports equipment and its associated biologically driven design aspects. However, all in all there was little general consensus on industry drivers – as many industry drivers were suggested as people attended sessions – pointing to a field with little in the way of common goals and experiences.

State of the Art

The state of the art in biomedical analysis is characterised by a relatively small amount of analysis work being carried out by companies and commercial organisations when compared with other industries. This work is often of a limited technical scope, being largely concerned with simple stressing of single components with simple loadcases. (The author has, in fact, visited an implant manufacturer without an in-house finite element program, and arguably no ability to use it either).

A factor which defines the Biomedical field is the dominant position of the University as a provider of analysis work. The reasons for this are manifold, however the leading role of the medical profession, and subservient position of the engineering staff who work with (for) them must have a bearing on how projects are carried out. Another factor which influences this bias is that the medical staff often have university positions and therefore have their analysis work carried out in there. Recent reports have pointed to government concern in the United States over the way in which implant manufacturers fund the research projects of the surgeons who use their products. This picture, coupled with use of university staff for analysis projects, means that biomedical FEA is carried out in a less than ordinary environment. Little wonder then that commercial analysis software has little in the way of features specifically aimed at this market. A significant proportion of the software used in the industry is bought under educational agreements, and the requests of this numerically small group, who pay a fraction of commercial rates for their software will obviously carry little or no weight when it comes to prioritising development plans. In many industries new techniques and approaches are developed in universities, which are then adopted in industry – in biomedical engineering the advanced techniques don't break away from the academic environment.

The insular, academic world of biomedical simulation may also go some way to explain the lack of contact with the traditional analysis world. Specific biomedical conferences and publications dominate the outlook; little time then, therefore, for another set of conferences and publications. This goes some way towards explaining the lack of interest in FENET from the biomedical world, at, it must be said, some cost as they have much to learn from other disciplines.

Whilst trying to canvas support for FENET amongst the UK biomedical industry another worrying trend became evident – the centre of gravity of technical operations of many biomedical companies has moved towards the USA. Some had moved their complete engineering operations to the USA – Zimmer for example, others had simply downsized their European engineering departments at the cost of their US operations.

6: CONCLUSIONS

FENET can be seen as a missed opportunity for the world of Biomedical Engineering; the field has a whole range of issues, some of which are shared with other arenas, other specific to biomechanics. It is evident that the biomedical arena is one with many different priorities and concerns to the other industry areas represented in FENET.