UK Focus for Biomedical Engineering

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UK Focus for Biomedical Engineering

Innovation in medtech - global reality and UK promise

Sir Christopher O’Donnell
November 2005
Global trends

• Demographics – ageing population
• Healthcare systems – managing rising costs
• Financial resources – need to offer patient benefit plus system value
• Emerging technologies – imaging/diagnostics, advanced biomaterials, active healing modalities
• Consumer awareness and active people/involvement increase – active people
Agenda

• Adoption curves for technology – UK uptake
• Innovation in medical technology
• Innovation at Smith & Nephew – three examples
• Factors affecting national innovation
• Encouraging UK medtech innovation - UK Healthcare Industry Taskforce
• Conclusions
Technology adoption life cycle

Bell shaped curve representing Rogers' (1995) findings on categories of individual level of innovation with percentages for each category.
Technology maturity curve – medtech sectors

Increasing Technology Maturity

<table>
<thead>
<tr>
<th>Embryonic</th>
<th>Growth</th>
<th>Mature</th>
<th>Ageing</th>
</tr>
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<tbody>
<tr>
<td>First “product” breakthrough</td>
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- IV Diagnostics reagents
- Active wound management
- Advanced wound management (Tissue engineering)
- Orthopaedics
- Imaging
- Elec.med/respiratory
- Radiotherapy

Market Size

- Pure scientific research in academia and public sector
- Privately funded internal and external development work
- Sales & marketing focus
- Internal incremental development work
- Cost reduction and production outsourcing

Source: Arthur D. Little
Uptake of innovative pharmaceuticals is slow in the UK

**Glivec (imatinib) sales uptake**
Units* per 1,000 population

Year 1 Year 2 Year 3 Year 4
France USA UK Germany

**Rebif (interferon beta) sales uptake**
Units* per 1,000 population

Year 1 Year 2 Year 3 Year 4 Year 5 Year 6
Germany France USA** UK

**Remicade (infliximab) sales uptake**
Units* per 1,000 population

USA France UK Germany

**Kineret (anakinra) sales uptake**
Units* per 1,000 population

Year 1 Year 2 Year 3
USA France*** Germany UK

* Standard dosage units (e.g. one vial). ** Rebif launched in 2002 in the US, therefore extended time series unavailable. *** Launched in France in 2003.

Source: IMS Midas Audits, 2005
Market share of new medicines 2003

Share of new products* 2003

USA: 28%
Germany: 23%
France: 21%
UK: 16%

* Products launched 1997-2002
Source: ABPI (IMS World Review). Slides provided by M Sheik, McKinsey
Access to medical technology is also low

Prostate cancer physicians with access to IMRT* facilities and expertise at their institution, 2003

<table>
<thead>
<tr>
<th>Country</th>
<th>Access (%)</th>
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<tbody>
<tr>
<td>Germany</td>
<td>47</td>
</tr>
<tr>
<td>France</td>
<td>44</td>
</tr>
<tr>
<td>USA</td>
<td>43</td>
</tr>
<tr>
<td>Spain</td>
<td>38</td>
</tr>
<tr>
<td>UK</td>
<td>16</td>
</tr>
</tbody>
</table>

* Intensity modulated radiation therapy.
Slides provided by M Sheik, Mckinsey
Medical technology market (€bn)

**World Market 2001 €170m**
- US: €73bn
- Europe: €47bn
- Japan: €24bn
- Rest of world: €36bn

**European Market 2002 €55m**
- Germany: €19bn
- France: €9bn
- Spain: €3bn
- UK: €6bn
- Italy: €6bn
- Rest of Europe: €12bn

Source: HITF Report 2004
European R&D investment (all industries) is low as a percentage of GDP

Taken from ‘Science and Innovation Investment Framework, DTI. July 2004
R&D spend in the medical device industry
- UK in the ball park but low in absolute terms

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales ($m) 2004</th>
<th>R&amp;D ($m) 2004</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zimmer</td>
<td>2981</td>
<td>167</td>
<td>5.6</td>
</tr>
<tr>
<td>ArthroCare</td>
<td>154</td>
<td>13</td>
<td>8.4</td>
</tr>
<tr>
<td>Stryker</td>
<td>4262</td>
<td>211</td>
<td>5.0</td>
</tr>
<tr>
<td>Biomet</td>
<td>1880</td>
<td>80</td>
<td>4.3</td>
</tr>
<tr>
<td>Medtronic</td>
<td>10055</td>
<td>951</td>
<td>9.5</td>
</tr>
<tr>
<td>UK medtech industry*</td>
<td>8125</td>
<td>686</td>
<td>8.4</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>2247</td>
<td>119</td>
<td>5.3</td>
</tr>
</tbody>
</table>

*2002 Data; £/$ = 1.80
Medtech innovation

At Smith & Nephew we have:

- A deep knowledge of materials science
- Strong biomaterials competence
- Active market scanning
- Increased customer insights
- State-of-the-art development processes
- Robust technology planning

Lead to:

- Genuine innovations and portfolio value
Innovation sourcing strategy

- Traditional, ‘transactional’ approach:
  - Ad hoc, opportunistic collaboration without analysis of alternative ways to reach the same goals
  - Failure to leverage organisational learning

- ‘Holistic’ approach
  - Overall innovation strategy including customer needs, technology trends, product portfolio management
  - Plan for use of internal and external sources to execute strategy
  - Sourcing principles to guide decision making

- S&N current practice:
  - Innovations are design, research or insights based
  - Technology plan communicates priorities
  - Moving towards customer focus – matching customer insights with technology mining and planning

Sources of new opportunities

Discovery process
- Identify non-obvious unmet needs
- Access wide range of technologies

Filtering process
- Down selection of ideas
- Validation of value propositions
- Sustainable differentiation

Traditional development programs
- Next generation products
- Product line extensions
- Predictable/typically incremental
- Fills almost all of commercial pipeline today

Research
- Can be paradigm shifting
- Big bets, scientific discovery often needed
Likely balance of innovation sourcing

• In a review of sources of innovation*, it was found that 45% of innovation in all companies included came from external sources, while for pharmaceutical firms the figure dropped to 30%

• 50% of new technologies in recent S&N orthopaedics projects have come from external sources

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Sources of Innovation for S&N Orthopaedics Research Project

50% Internal
- e.g. OXINIUM® high performance bearing surfaces – Orthopaedics R&D
- e.g. Cross-linked polyethylene – R&D

50% External
- e.g. EXOGEN® – Commercial technology offering
- e.g. VERSABOND® – bone cement: Commercial technology offering

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Innovation – the total process

Discovering Combinations
Active creation & prequalification of new combinations

Selection
Rigorous evaluation against value & differentiation screens

Adaptive Strategic Positioning
Building, adapting & proving the business model

Commercialisation
Move through established development pipeline and successful commercial launch
Innovation at Smith & Nephew – three examples

• Orthopaedic implants - OXINIUM°
• Arthroscopy - bioresorbables
• Fracture healing - EXOGEN°
• Smith & Nephew key competence – help to heal and repair human tissue
A new high performance orthopaedic implant material - OXINIUM™

- Patient demands are increasing:
  - Average age of patients is decreasing
  - Patients expect function-recovery, not just pain relief
- Greater longevity and functionality of total knee replacement implants is required
- Wear debris is a significant factor in aseptic loosening of total knee arthroplasty implants
- Aseptic loosening of total knee arthroplasty implants is a leading cause of implant failure
- So wear must be reduced as much and as safely as possible to help implants last longer
OXINIUM° – a major innovation

• Ceramic is generally accepted as the ideal bearing surface for total joints but has strength limitations

• For more than 15 years Smith & Nephew has been working to develop an innovative material that combines the benefits of ceramic with the strength of metal

• The result of our efforts is the first true breakthrough the industry has seen in decades: OXINIUM°, a metal with an integral ceramic surface

• OXINIUM° is the first and only metal specifically engineered as a high-performance bearing surface

• Performing clinically equivalent to or better than CoCr
  – First total knee in Dec. 1997; over 70,000 implanted
  – First total hip in Oct. 2002; over 30,000 implanted
Properties of OXINIUM° implants

1. Superior Abrasion Resistance
   - OXINIUM° technology is 4,900X more resistant to abrasion
   - OXINIUM° technology was 160X smoother after test

2. Increased Hardness
   - Harder = resistant to scratching
   - OXINIUM° Technology is over twice as hard as CoCr

3. Lower Friction
   - Lower Coefficient = increased sliding efficiency which may reduce wear
   - OXINIUM° surfaces produce up to 50% less friction against PE than do CoCr surfaces
OXINIUM° market potential

Market growth from new early intervention knee systems

Market growth from new JOURNEY° high demand knee system

Continued market growth of GENESIS II°, PROFIX°, Unicondylar Knees and Femoral Heads
Arthroscopy innovation timeline

1950s
- Rod lens system invented
- First partial menisectomy performed

1960s
- Dr. Wantabe develops first production arthroscope

1970s
- Needle scope
- Rotating suction shaver
- Televideoscopy
- Move from diagnostic to surgical mode

1980s
- Autologous osteochondral transplantation
- 3D scopes
- Hip arthroscopy
- Electronic endoscopes

1990s
- 3D scopes
- Hip arthroscopy
- Autoclavable endoscopes

2000s
- Cell based therapies
- Active agents
- Smith & Nephew

2010+
- Gene therapy
- European Innovations
- Japanese Innovations
- Future possibilities

Smith & Nephew
US Innovations
Arthroscopy innovation
- less invasive/accelerated healing: Bioresorbables

- PLLA-HA
  - BIORCI™-HA
  - TWINFIX™ AB 5.0
  - ENDOFIX™-L
  - BIORCI™
  - TWINFIX™ AB 6.5
  - FAST-FIX’ AB
  - SURETAC™ III

- PLLA
  - SURETAC™ II w/Spikes
  - ENDOFIX™
  - TAG™ Wedge, TAG™ Rod II

- Maxon-B
  - SURETAC™
  - Mini TAG™

- Osteoconductive material
  - PLLA-HA
  - PLLA
  - Maxon-B

Year:

New Anchor

SURETAC™ III
TWINFIX™ AB 5.0
BIORCI™-HA
BIORAPTOR™
Arthroscopy innovation
- less invasive/accelerated healing: Bioresorbables

Material properties

- Polymers are designed to match the healing profile of the tissue they are repairing
- As the repair process occurs the load is progressively transferred from the device to the repair tissue

In vitro Strength Retention of Bioabsorbable Polymers

![Graph showing in vitro strength retention of bioabsorbable polymers over time.](image)
Arthroscopy innovation
- less invasive/accelerated healing: SURETAC™

- Bioabsorbable tack used for reattachment of soft tissue (labrum) to bone in the shoulder
- Polyglyconate: (67% PGA / 33% TMC) PGA - polyglycolic acid; TMC – Trimethylene Carbonate
- Shoulder Repair: Arthroscopic reattachment of labral tissue to glenoid rim (no sutures or knots required)
- First bioabsorbable implant device on the sports medicine market
- Toughest absorbable polymer on market.
- Degrades to zero strength over the healing period (4 to 8 weeks) and is absorbed by the body in approximately 1 year
- Has been updated twice to meet market needs
- Over 290,000 SURETAC™ devices have been successfully implanted since its launch in 1992
An innovative advance in fracture treatment - EXOGEN°

- Non-invasive therapy for improving the healing of fractures
- Low intensity pulsed ultra-sound applied for 20 minutes per day
- Supported by two randomised, double blind, placebo controlled, multi-centred clinical studies
- Efficacious in both cortical and cancellous bone
- Over 80,000 patients treated

- Low-Intensity (30mW/cm²)
- Lower Intensity than Foetal Sonogram
- Non-Thermal Signal (no heat)
Clinical data

Tibial diaphysis fractures were treated in a prospective, randomised, double-blind, placebo-controlled, multi-centre study*.

33 patients had the ultrasound treatment; 34 had placebo

38% faster time to healed fracture:
active - 96 days; placebo 154 days (P<0.0001)

83% reduction in incidence of delayed unions

EXOGEN° mechanism of action

- Produces a mechanical signal (vibration)
- Transmits through soft tissue and through and around the bone
- Produces nano-motion at the fracture site
- Detected by integrins at the cell surface
- Affects a range of cells important to fracture healing
- Initiates an intra-cellular cascade resulting in a range of key proteins being produced
- Accelerates or re-initiates the natural fracture healing process
- Beneficial at all stages of the fracture repair process
- Maximum impact when applied throughout the healing process
EXOGEN™ market potential

Exploit understanding of mechanism and extend into soft tissue indications

Capitalise on fresh fracture opportunity through effective clinical, regulatory and reimbursement programmes supported by basic science

Continue market share growth in non-unions through effective sales and marketing
Innovation is global – we think about it and deliver it globally

- Mayo Clinic, Rochester, USA
- Rush University, Chicago, USA
- Original inventive work - Brazil
- Regensburg Germany
- University of NSW, Australia
- Saito, Japan
- Naruse Mikuni-Takagak, Japan
- Teijin Pharma, Japan
- Chang Gung Hospital, Taiwan
- Leung, Hong Kong
- ACTA-Vrije Uni Netherlands
- OMC, UK
- Ulm University Germany
- EXOGEN® mode of action - academic collaborators
Factors affecting national ability to innovate/differentiate products

1. Differences in customer demand:
   - Levels of healthcare spend per capita
   - Approval, procurement and reimbursement practices
   - Clinical practice, medical training and healthcare philosophies

Source: Arthur D Little/ DTI report 2004
Factors affecting national ability to innovate/differentiate products

2. Access to scientific/clinical knowledge:
   - Varies according to maturity of technology
   - Clinicians have multiple linkages with innovation process

Source: Arthur D Little/DTI report 2004
Factors affecting national ability to innovate/differentiate products

3. Global suppliers access scientific knowledge globally:
   • Top four suppliers have 50-75% of global sales in each sector
   • Top tier suppliers utilise global outreach to scientific community
   • Reduces markedly product differentiation between countries

Source: Arthur D Little/ DTI report 2004
UK Healthcare Industry Task Force – “Better health through partnership”

The trigger:
“The NHS was a late and slow adopter of medical technology”

The Aim:
“To capture the best that the NHS, social care and industry can provide for the benefit of the health of the nation”

The Timing:
The HITF Report was completed and issued in November 2004.

UK Healthcare Industry Task Force: outputs

1. Device Evaluation
   
   **Aim:** Encourage the uptake of useful, safe, innovative products and procedures in health and social care
   
   **Action:** Move Device Evaluation Service to the NHS Purchasing and Supply Agency to take this responsibility
   
   **Status:** In place – delivery to be demonstrated
   
   **Potential issue:** Department of Health Supply Chain initiatives have cost reduction rather than innovation or value as objectives
UK Healthcare Industry Task Force: outputs

2. Innovation

Aim: Stimulate more innovation and encourage a more entrepreneurial culture in industry and the NHS

Action: Develop a National Innovation Centre – established within the new NHS Institute for Improvement and Innovation

Status: In place – delivery to be demonstrated
UK Healthcare Industry Task Force: outputs

3. Related Initiatives

- Incorporate medical devices into the UK Clinical Research Collaboration
  Status: In place

- Develop a pilot Healthcare Technology Centre to pioneer specialist techniques in patient treatment
  Status: Under consideration

- Work towards improving training and education on medical devices for NHS staff
  Status: Incorporated in NHS Institute and National Innovation Centre programme – more to do!
Conclusions

• Medical technology is a large and growing global industry
• Innovation is the key driver of growth and is global in nature
• Technology plays a major role in driving this innovation
• The UK market is small (3%) in a global context – and the UK is a “slow and late adopter of medical technology”
• Government and industry have established a partnership to try to accelerate innovation in the NHS and the UK medtech industry
• The opportunities are large – but the route is challenging!
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