60 years of Pacemaker Therapy
Still going strong!
Past, Present and Future

Richard Sutton
Emeritus Professor of Clinical Cardiology
Imperial College, London, UK
Cardiac Pacing

The Past

First implant 1958 Sweden
Dual Chamber pacing (VAT) 1962 US
Transvenous VDD pacing Europe/US 1976
DDD pacing 1978 Germany
Large clinical trials in Pacing 1980s–2005 Europe/US
>500,000 Pacemaker Implants/Year
Pacing for heart failure 1994 France
Large clinical trials of Resynch Europe/US 2001-pres
Dr. Elmqvist - engineer - constructed two pacemakers.

Dr. Senning - surgeon - did not realize (nor did anyone) that electrocautery could damage the device’s transistors (two).

Mr. Larsson’s need for pacing was intermittent. Three hours post-op, he had another spell when the pacemaker was found non-functional.

Within the first 24 hours, Mr. Larsson received the world’s second fully implanted pacemaker.
Earl Bakken’s garage
Earl Bakken in his garage
Chardack-Greatbatch implantable pacemakers c 1960
Some early manufacturers

American Optical

General Electric

Cordis
1958 and 2008 comparison
1958 to 2008 – Comparison of Implant Procedure

Open thoracotomy
General anaesthesia
3 to 4 hours
Weeks in hospital

Leads inserted through vein
Local anaesthesia / sedation
1 hour
Same day discharge
1958 to 2008 – Comparison of Size and Components

38 cc, 83 grams
24 cm², 16 mm thick
2 transistors
Longevity < 1 yr

12 cc, 29 grams
19 cm², 6.0 mm thick
20,000,000+ transistors
Up to 20 years, at least 5 yr
1958 to 2008—Comparison of Programmability

Modes of operation: 1 (preset)
Rates: 1 (preset)
Rate Response: None
Parameter combinations: 1

Over 20
30 to 180 pulses/min
Tailored to patient
Trillions
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The Future

Which areas will develop?

Any areas which will contract?

What are the threats to pacing?
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AV Block
Sinus Node Disease
Carotid Sinus Syndrome

are all diseases occurring in older age

The population is ageing in the West which will later occur in developing countries
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Reaching patients with conditions which will benefit from pacing is still far from complete

In Europe, obvious examples are UK, Ireland, Netherlands and Switzerland
Many Western populations appear to be under-paced

Total IPG Eucomed 2005 implants per million in W. Europe

Germany
Belgium
Italy
France
US
Austria
Sweden
Denmark
Portugal
Spain
Switzerland
Finland
Netherlands
Ireland
UK
Norway

These data include replacements which are estimated at 20%
Many Western populations appear to be under-paced.
High implant rates vs. low implant rates (2005)

- Germany
- Belgium
- France
- Switzerland
- Netherlands
- UK

Implants per Million
Implants per million vs. calculated incidence per million
(new implants now only considered)

<table>
<thead>
<tr>
<th>Country</th>
<th>Current Implanted Incidence</th>
<th>Current Calculated Unimplanted Incidence</th>
<th>Calculated Incidence</th>
<th>Calculated Incidence Percentage</th>
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</thead>
<tbody>
<tr>
<td>Germany</td>
<td>906</td>
<td>29</td>
<td>935</td>
<td>97%</td>
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<tr>
<td>Belgium</td>
<td>843</td>
<td>71</td>
<td>913</td>
<td>92%</td>
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<td>France</td>
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<td>Spain</td>
<td>539</td>
<td>412</td>
<td>951</td>
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<tr>
<td>Switzerland</td>
<td>519</td>
<td>329</td>
<td>847</td>
<td>61%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>471</td>
<td>253</td>
<td>724</td>
<td>65%</td>
</tr>
<tr>
<td>UK</td>
<td>400</td>
<td>478</td>
<td>878</td>
<td>46%</td>
</tr>
</tbody>
</table>
Implants per million 2003-2005

- Germany
- Belgium
- France
- Spain
- Switzerland
- Netherlands
- UK
% of total population aged 65+ across Western Europe, Year 2000 to 2050 – UN data

- Germany
- Belgium
- France
- Spain
- Switzerland
- Netherlands
- UK

Year 2000: 0%
Year 2025: 15%
Year 2050: 30%

1. Germany
2. Belgium
3. France
4. Spain
5. Switzerland
6. Netherlands
7. UK

Legend:
- 2050
- 2025
- 2000
Low-implant rates compared with calculated need

- Possible explanations
  - Different populations – based on age (NL & Eire younger)
  - Lack of diagnosis
  - Lack of application of appropriate technology in diagnosis and treatment

- Why?
  - Underdeveloped medical system
  - Insufficient numbers of cardiologists
  - Poor training
  - Hostility to referrals
  - Lack of facilities
  - Uneducated patient population
Conclusion: we may think we are implanting enough pacemakers in W. Europe, but we are, in many cases, not doing this even in recent years

How to overcome?
• More cardiologists
• Better training of doctors at all levels (family doctor and up)
• Better continuing education at all levels
• Better facilities
• Better use of appropriate technology
• More patient education
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Carotid Sinus Syndrome

Still greatly underdiagnosed

Not investigated by most physicians

Two estimates in early 1980s of the Incidence 35-40 new cases/million/year

Almost certainly more than this: EP community needs to refocus
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Population is increasingly becoming obese

Obesity is strongly associated with Sleep Apnoea

Sleep Apnoea probably causes

Arrhythmias esp. Sinus Node Disease
Hypertension
Sleep Apnoea can be addressed in many ways

1. Detection

2. Better treatment of complicating arrhythmias

3. Better treatments of the condition itself
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Neurally Mediated Syncope – Recent Events

Trials of pacing for VVS initially favourable

Failed to demonstrate benefit when all patients received a pacemaker randomized to ‘ON’ or ‘OFF’

Why?
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The answer does not lie in placebo effect rather in inappropriate patient selection
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Potential for pacing in VVS
Story begins with VASIS and ISSUE 1

1. European selection for trials has typically been of patients >15 years older than N America

2. ISSUE 1 demonstrated that tilt testing less reliably reveals asystole in contrast to use of ILRs
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Pacing in VVS

ISSUE 2, a registry, suggested that

In patients of mean age 63 registration of asystole in a spontaneous attack will result in successful subsequent use of pacing

ISSUE 3, a RCT, has confirmed this. Older patients (~60yrs) will have benefit especially if ILR shows asystole in an attack but tilt test negative
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Pacing in VVS

The message is that VVS in older patients is a disease, perhaps caused by a degenerative process in the autonomic nervous system’s cardiac control.

Quite different from the VVS phenomenon in young people.

This understanding makes it amenable to successful pacing therapy especially if vasodepression is not severe.
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Pacing in VVS

In an ageing population the need for pacing could be 50 new cases per/million/year.

Emphasis on NMS both CSS and VVS could add 10-20% increase in pacemaker use.
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Developing areas in developed countries

Better application of pacing in SND/AVB + CSS + NMS

900-1000 implants/m/y → 1000-1100
400-600 implants/m/y → 1000-1100
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Developing areas in less developed countries

Potential is enormous to approach that in the West but finances lacking.
To this end
  Older pacer models to be maintained
  New simpler models omitting sophisticated options of limited benefit
  Implant without the use of X-ray fluoroscopy
  Hub and spoke
  Self-help plus outside help
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Areas which will contract

1. Long term less ischaemic disease so less AV Block but patients will live longer and be exposed to other causes of AV Block

2. AV Junctional ablation is now rarely practised except in AF + CRT
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Threats to technology of cardiac pacing

Stem cell therapy

A. Ways presently difficult to conceive; need for AV conduction
B. Sources of atrial and ventricular depolarisation

Problem is coordination of ‘new’ pacemaker with:

A. Patient’s autonomic control system
B. With other cell sources
e.g. A-V sequence
    Resynchronisation of ventricles
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Threats to technology of cardiac pacing

Bio-electric power sources

Not such a threat because, if successful, will still need many aspects of pacing technology
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Threats to delivery of pacing therapy

Healthcare systems and bodies such as UK’s NICE

New therapy must be justified by clinical trial

New therapy must demonstrate cost-effectiveness

All of these are expensive
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Better pacing

Avoidance of ventricular stimulation except when necessary implying minimization of ventricular pacing by algorithm

HIS bundle pacing especially has a growing role in CRT

Avoid causing heart failure by RV stimulation at apex

Leadless pacing now single – soon dual Cosmetically better, less sepsis, no lead fractures
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Better pacing

Using sensors to optimize the benefit from pacing has happened but still improving

Using sensors to warn when patient’s condition is deteriorating prompting changes in stimulation pattern
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Better pacing

Home monitoring to permit adaptation of the system to the patient and be able to anticipate future problems
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Better pacing

Better resynchronization including His or LV pacing
Multiple ventricular sites
Effective AV synchrony considering LV delay
Solve problem of non-responders to CRT
MRI compatible devices
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Could cardiac desynchronization by pacing have value?

- Hypertrophic Cardiomyopathy
- Hypertension
- Vasovagal Syncope
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Major challenges in Cardiology are:

1. Prevention of hypertrophy - BP control

2. Prevention of fibrotic areas (scars)
   - Primary angioplasty
   - Stem cell therapy?
   - Stabilisation of vulnerable plaque
   - Combat inflammation

3. Prevention of calcification in the heart. Pacing susceptible tissue in absolute refractory period may have preventative value
Conclusions

Pacing has come a long way since 1958

State of pacing is healthy and offers improved health

Pacing will grow not contract: much work needs to be done

Pacing will become more patient-friendly

May be further applications of stimulation technology