Development of the Electroanatomical Mapping System

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Stages in the Development and Clinical Use of the Carto System

- Conception of the idea, technology development, preclinical studies
- Initial human studies
- Development of mapping and ablation strategies for complex arrhythmias
- Ablation for atrial fibrillation
- Related technological developments (imaging, ablation technologies)
Shlomo Ben-Haim

Founds Biosense in Haifa, Israel in 1993

First clinical cases – November 1995

Johnson & Johnson buys Biosense, Inc. in 1997

Johnson & Johnson merges Biosense, Inc. and Cordis Webster in 1998
Innovation Requirements

- Clinical problem/need
- Market
- Innovative idea/technology
- Innovative environment
- Funding/ business plan
Innovations in Israel

- Medical patents/capita
- BioPharma patents/capita

Bar charts comparing medical and bioPharma patents per capita for various countries, including Israel.

Innovations in Israel

- **Teva Industry**
  - Copaxon, Azilect

- **Stents**
  - InStent, Nir, Many more

- **Biosense**
  - Revolutionized EP

- **Given Imaging**
  - Revolutionized GI diagnosis

- **Ventor**
  - Novel Transapical Valve
Cardiac Mapping

- Mapping is a general term that relates to the assignment and display of encoded-information according to its spatial coordinates.

- Cardiac Mapping:
  - Spatial coordinates of the recording sites
  - Electrophysiological information

- Beat-by-beat single site vs. multi-site recording
Finger electrode
Epicardial sock
Cardiac mapping history-3

- Catheter mapping
  - fluoroscopic location
  - basket
  - non-contact
The Navistar Catheter

Locatable tip:
- Real-time
- Six degrees of freedom
The Location Pad

- An External Ultra-Low Magnetic Field Emitter
Carto Locatable Catheter

- Magnetic Sensor, Real time
- 6 degrees of freedom; location and orientation
- Statistic *in vitro*
  accuracy: 0.2 mm
- Statistic *in vivo*
  accuracy: 0.7 mm

Surface Reconstruction
Surface Reconstruction

System records location through constant interrogation of the magnetic field generated from the location pad
Surface Reconstruction

Records location 2
Surface Reconstruction

Records location 3
Surface Reconstruction

- Superimposes point location and local activation times
The initial phase: matching an ellipsoid to the acquired points. Bounding all the points with an egg shell shape.

The second phase: Stretching and bending the shell to fit the points.
When each point is added, the shape of the reconstruction is updated.

The shape of the chamber is stretched and bent to intersect through the real points locations.
Surface Reconstruction
Surface Reconstruction

To compensate for patient X, Y, Z movements and respiration
Point Acquisition

- Each point has location and electrical information associated with it
- While adding points, each point is connected to neighboring points
- Electrical activation is interpolated between points
- A 3D color-coded map is created
Gepstein et al. Circulation 1997

Table 1. Point Ablations in Swine RA

<table>
<thead>
<tr>
<th>Experiment No.</th>
<th>Area Shape</th>
<th>Dimensions, mm</th>
<th>Area, mm²</th>
<th>Ablation Point Distances, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ellipse</td>
<td>8 x 5</td>
<td>31.4</td>
<td>0, 3, 3</td>
</tr>
<tr>
<td>1</td>
<td>Ellipse</td>
<td>9 x 5</td>
<td>35.3</td>
<td>0, 5, 0</td>
</tr>
<tr>
<td>2</td>
<td>Circle</td>
<td>10</td>
<td>78.5</td>
<td>5, 5, 3</td>
</tr>
<tr>
<td>3</td>
<td>Ellipse</td>
<td>12 x 3</td>
<td>28.2</td>
<td>0, 0, 0</td>
</tr>
<tr>
<td>4</td>
<td>Ellipse</td>
<td>9 x 4</td>
<td>28.3</td>
<td>5, 2, 4</td>
</tr>
<tr>
<td>5</td>
<td>Ellipse</td>
<td>15 x 10</td>
<td>117.8</td>
<td>4, 8, 6</td>
</tr>
<tr>
<td>6</td>
<td>Ellipse</td>
<td>11 x 8</td>
<td>69.1</td>
<td>3, 4, 7</td>
</tr>
<tr>
<td>7</td>
<td>Circle</td>
<td>5</td>
<td>19.6</td>
<td>0, 0, 0</td>
</tr>
<tr>
<td>8</td>
<td>Circle</td>
<td>4</td>
<td>12.6</td>
<td>0, 0, 0</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td></td>
<td>46.8</td>
<td>2.3</td>
</tr>
<tr>
<td>SEM</td>
<td></td>
<td></td>
<td>11.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Minimum</td>
<td></td>
<td></td>
<td>12.6</td>
<td>0</td>
</tr>
<tr>
<td>Maximum</td>
<td></td>
<td></td>
<td>117.8</td>
<td>8</td>
</tr>
</tbody>
</table>

Each point ablation was repeated three times (A, B, and C) in an attempt to navigate to the same site.

Table 2. Linear Ablations in Swine RA

<table>
<thead>
<tr>
<th>Experiment No.</th>
<th>RA Line Ablation Dimensions, mm</th>
<th>NFM RA Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Line Length</td>
<td>Line Width, Minimum-Maximum</td>
</tr>
<tr>
<td>1</td>
<td>26.0</td>
<td>3.0-5.5</td>
</tr>
<tr>
<td>2</td>
<td>20.0</td>
<td>4.5-6.5</td>
</tr>
<tr>
<td>3</td>
<td>28.0</td>
<td>4.0-6.5</td>
</tr>
<tr>
<td>4</td>
<td>29.0</td>
<td>4.5-7.0</td>
</tr>
<tr>
<td>5</td>
<td>24.0</td>
<td>3.5-8.0</td>
</tr>
<tr>
<td>6</td>
<td>37.0</td>
<td>3.0-4.0</td>
</tr>
<tr>
<td>Mean±SEM</td>
<td>27.3±2.3</td>
<td>3.9-6.7</td>
</tr>
</tbody>
</table>

Each line of ablation was obtained from 6 to 12 individual point ablations.
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- Additional technological developments
- The future
New Method for Nonfluoroscopic Endocardial Mapping in Humans
Accuracy Assessment and First Clinical Results

Joep L.R.M. Smeets, MD; Shlomo A. Ben-Haim, MD; Luz-Maria Rodriguez, MD; Carl Timmermans, MD; Hein J.J. Wellens, MD
Mapping in Humans
Stages in the Development and Clinical Use of the Carto System

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Three-Dimensional Mapping Systems

- Understanding the mechanism of the arrhythmia and the underlying substrate
- Defining the anatomy
- Designing an ablation strategy
- Delivering the therapy (ablation)
- Assessment of the lesion
Mapping Methods: Electrophysiological information

- Activation mapping
- Propagation maps - videos
- Voltage mapping
- Pace mapping
- Entrainment
- Fibrillation indices: FFT, Fragmentation index
Activation Mapping
Activation Mapping

- Macro reentrant arrhythmias
  - Mapping of the full cycle-length of the arrhythmias
  - Head-meets-tail
- Focal Arrhythmias
  - Total activation time $< CL$
  - Early (red) surrounded by later sites
Focal Arrhythmias
VT in Infant
VT in Infant
Macro Reentrant Arrhythmias

Mapping Methods: Electrophysiological information

- Activation mapping
- Propagation maps - videos
- Voltage mapping
- Pace mapping
- Entrainment
- Fibrillation indices: FFT, Fragmentation index
Scar-related Atrial Tachycardias
Scar – Inferior Myocardial Infarction
ARVD- Voltage Mapping

Boulos, Gepstein. J Am Coll Cardiol 2001
Hemochromatosis
Three-Dimensional Mapping Systems

- Understanding the mechanism of the arrhythmia and the underlying substrate
- Defining the anatomy
- Designing an ablation strategy
- Delivering the therapy (ablation)
- Assessment of the lesion
Isthmus ablation for atrial flutter
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CT/MR Imaging

- Three-dimensional volume/surface reconstruction of cardiac chambers and big vessels from 2D raw data CT/MR scan
FAM vs. EA map done in Gated mode
GUI: Force Value and Direction  

Below Threshold  

Within Threshold  

Above Threshold  

Note the vector that is colored according to the force values defined by the thresholds.
The Future

- Better understanding of patient-specific arrhythmia mechanism (atrial fibrillation)
- Non-destructive treatments
  - Gene therapy
  - Cell therapy
  - “Conducting cables”
  - “Molecular ablation”
Correlation with Pathology

Gepstein et al., Circulation (1998)
Thanks:
Shlomo Ben-Haim
Biosense engineers
Gal Hayam, Shlomo Shpun
Rona Shofti, Edith Cohen
Thank You