New Technologies for AF Ablation: Do they add value?
Contact Force Ablation Catheters

Karl-Heinz Kuck

Hanseatic Heart Center
St. Georg Hospital in Hamburg, Germany
## Disclosure Statement

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>Research Grants</td>
<td>Biosense Webster, Stereotaxis, Medtronic, St. Jude, Cardiofocus, Abbott</td>
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<td>Consultant / Advisory Board</td>
<td>St. Jude, Edwards, Stereotaxis, Mitralign, Cardiofocus, BMDSys, ACT, Maya, Apama, Topera, Recor, Endosense, SynapticMed,</td>
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<td>Ownership Interests</td>
<td>Shareholder Endosense</td>
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<td>Speaker’s Bureau Honoraria</td>
<td>Biosense Webster, Medtronic, St. Jude, Abbott, Cardiofocus, Biotronik</td>
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<td>Fellowship Support</td>
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<td>Other</td>
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<td>Off-label drugs/devices</td>
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- Clinical Study Results
  - TOCCATA
  - EFFICAS I
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  - Single center studies
- Lesion Index real-time measurement
Why Contact Force?

- Temperature (°C)
- Duration (s)
- Power (W)
- Contact force (g)

Known values

Path to Guidelines
Direct contact force measurement

TactiCath Quartz, Endosense

- No calibration plug and play
- Dedicated interface all Contact Force information at once
- 50 Hz sampling rate real-time highly accurate information
ThermoCool Smart Touch™ catheter design -

TRANSMITTER coil in the tip sends location reference signal.

PRECISION SPRING allows small amount of electrode deflection.

SENSORS receive transmitter coils location signal and micro-movements of the spring.
Path to contact force guidelines

Clinical Results Endosense

**TOCCASTAR IDE Study**  
- Effectiveness and Safety with TactiCath™  
- Randomized

**EFFICAS II**
- Significant better outcome at using Contact Force guidelines

**EFFICAS I**  
- Published  
- Contact Force guidelines  
  - Minimum Contact Force  
  - Minimum Force Time Integral

**TOCCATA**  
- Published  
- Safety and feasibility of Force Sensing  
- Importance of Average Contact Force and Force Time Integral
TOCCATA RESULTS
HIGH VARIABILITY WITHOUT CONTACT FORCE

HAVE OUR HOPES BEEN REALIZED WITH CF?
TOCCATA RESULTS: BETTER CLINICAL OUTCOME WITH CONTACT FORCE

There is a significant relationship between AF recurrence at 12-month and Contact Force applied during ablations.

EFFICAS I – OUTCOME
FORCE TIME INTEGRAL AS SUCCESS FACTOR

Relationship between Min FTI and % of gap in PV segments

- **Min FTI < 400 gs**
  - N=224
  - 79% No gap in PV segment
  - 21% Gap in PV segment
- **Min FTI > 400 gs**
  - N=94
  - 5% No gap in PV segment
  - 95% Gap in PV segment

<table>
<thead>
<tr>
<th>Parameter (per segment)</th>
<th>Median NO GAP N=266</th>
<th>Median WITH GAPS N=52</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CF</td>
<td>19.5 g</td>
<td>15.5 g</td>
<td>p = 0.022</td>
</tr>
<tr>
<td>FTI</td>
<td>708 gs</td>
<td>627 gs</td>
<td>p = 0.090</td>
</tr>
<tr>
<td>Total number of ablations</td>
<td>6</td>
<td>9</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Min CF</td>
<td>8.1 g</td>
<td>3.6 g</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Min FTI</td>
<td>232 gs</td>
<td>118 gs</td>
<td>p &lt; 0.001</td>
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Neuzil P, et al. Electrical Reconnection Following PVI is Contingent on Contact Force during Initial Treatment - Results From the EFFICAS I Study. Circ Arrhythm Electrophysiol. 2013; 6: 327-333
FIRST STEP TO CONTACT FORCE GUIDELINES

Long-term isolation can be achieved in 85% of the veins when ablated following contact force recommendations in EFF II

Without CF: 72% (EFF1, n=102)
Using CF guidelines: 85% (EFF2, n=91)

- TARGET 20 g with range [10 g, 30 g]
- Min > 10 g for any ablation point
- Min > 400 gs for any ablation point
- ONE SHOT → Transmurality should be achieved in one shot

Kautzner et al. EFFICAS II results. Oral presentation HRS 2012
Neuzil P, et al. Electrical Reconnection Following PVI is Contingent on Contact Force during Initial Treatment - Results From the EFFICAS I Study. Circ Arrhythm Electrophysiol. 2013; 6: 327-333

CONFIDENTIAL
Durable isolation of veins with low Jump-Index

When treated with CF guidelines & continuous set of ablations
98% of veins are isolated at 3M follow-up in EFFICAS II

% Veins isolated

<table>
<thead>
<tr>
<th></th>
<th>EFF1</th>
<th>EFF2</th>
</tr>
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<tbody>
<tr>
<td>Without CF</td>
<td>81%</td>
<td></td>
</tr>
<tr>
<td>Using CF guidelines</td>
<td></td>
<td>98%</td>
</tr>
<tr>
<td>p=0.005</td>
<td></td>
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</tbody>
</table>

JI filter
High Continuity: Low JI (<6)

TARGET 20 g with range [10 g, 30 g]

Min > 10 g for any ablation point

Min > 400 gs for any ablation point

ONE SHOT ➔ Transmurality should be achieved in one shot

Continuous Lesions ➔ Low Jump-Index

Kautzner et al. EFFICAS II results. Oral presentation HRS 2012
Jump index quantification

- Methodology to count jump: count the number of position jumped over between 2 consecutive ablations

- Ablation on Carina is counted as if catheter was jumping over 2 positions

- Jump index stops incrementing as soon as every position is ablated once
**SUPERIOR PROCEDURE EFFICIENCY WITH CONTACT FORCE**

- **EFFICAS II**
  - 100% of targeted veins isolated acutely
    - Wissner et al. EFFICAS II results. Oral presentation AHA 2011

- **Confirmed by independent studies**
  - Real Time Contact Force Measurement during AF Ablation Procedures - New Insights from a Single Center Experience
    - R. Wakili, et al., Augsburg, Clin Res Cardiol 101, Suppl 1, April 2012
    - **LA procedure time reduction**: -22%
      - Tacticath: 74.18 min
      - Control: 95.43 min, p<0.05
    - **Number of RF applications reduction**: -23%
      - TactiCath: 35.56
      - Control: 45.89, p< 0.05

  - Force controlled RF ablation increases Effectivity for AF ablation using PV isolation
    - J. Schreiek et.al., Tubingen, Germany, Clin Res Cardiol 101, Suppl 1, April 2012
    - **LA procedure time reduction**: -32%
      - Tacticath: 98 ± 37 min
      - Control: 145 ± 41 min (p<0.01)
    - **Clin. success for 1 procedure at 8±3 m. +15%**
      - TactiCath: 75% (n=36)
      - Control: 60% (n=72)

  - Catheter Contact in AF ablation: what benefit can we earn?
    - **RF ablation time reduction**: -35%
      - Tacticath: 19.9 ± 7.8 min
      - Control: 30.9 ± 10.9 min (p<0.001)
Methods

• CF during point-by-point LA mapping were assessed in 50 patients.
• In 30 patients, the operators were blinded to the CF during the procedure (Group A).
• In 20 patients, the CF was displayed to the operators (Group B). Aim was a CF of 10-40g.
• The catheter remained for at least 2 seconds at one mapping point prior to the point acquisition. CF was averaged every 50 ms. For each mapping point, data over 1.2 second period (resolution <1g) were acquired.
Catheter to tissue CF during LA mapping

Makimoto, Tilz et al, submitted
Contact force during ablation

Figure 4

Median CF

30g ≤ Median CF
20g ≤ Median CF < 30g
10g ≤ Median CF < 20g
Median CF < 10g

Makimoto, Tilz et al, submitted
Comparison of CF Between Blinded and Non Blinded LA Mapping

Average CF (g)

- Non Blinded
- Blinded
Treatment of PVI with Contact Force results in significantly less acute reconnections

First clinical study with SmartTouch
- Reconnections 1h post procedure reduced with CF ablation
- Gaps occurred at areas of low CF
- Single center, 40 pts

"Conclusions: Availability of real time CF information during PVI was associated with a significantly lower acute PV reconnection rate"

Haldar S, et al, Contact force sensing technology identifies sites of inadequate contact and reduces acute pulmonary vein reconnection. Int J Cardiol (2012)
22% of RF ablations without CF do not create lesions

- Ventricular ablations in sheep model, 30W, 60s
- Experienced operator, confirming impression of good contact based on tactile feed-back, fluoroscopy and EGM
- 100% of lesions detected if CF > 10g and FTI>500gs
- FTI most accurate parameter to predict lesion size

“Conclusions—In the absence of CF feedback, 22% of endocardial radiofrequency applications that are thought to have good contact did not result in lesion formation”

<table>
<thead>
<tr>
<th></th>
<th>ThermoC (n=80)</th>
<th>TactiCath (n=80)</th>
<th>ThermoC (n=68)</th>
<th>TactiCath (n=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions detected</td>
<td>78%</td>
<td>98%</td>
<td>90%</td>
<td>100%</td>
</tr>
<tr>
<td>p</td>
<td>&lt; 0.001</td>
<td></td>
<td>0.02</td>
<td></td>
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TOCCASTAR PIVOTAL STUDY

• **First CF sensor randomized IDE study**
  – Full enrollment completed: 300 patients (1/3 EU, 2/3 US)
  – PI: Dr Vivek Reddy, Mount Sinai Medical Center, NY
  – No need for additional clinical data to obtain Quartz approval
  – Additional 30-50 Quartz procedures to support enhanced Quartz user interface
  – 12 month f.u. completed June ‘13, approval anticipated July 2014

• **Primary endpoints**
  – Safety and Effectiveness (non-inferiority) at 12 months

• **Secondary endpoints**
  – Time from first ablation to PV isolation
  – # gaps after 30 minutes waiting
  – RF application time
TOCCASTAR vs TOCCATA, key Contact Force indicators

Average CF [g] over all ablations

Partially filled bar chart showing:
- TOCCASTAR: 8836 ablations
- TOCCATA: 986 ablations

Percent Lesions with Low CF (< 5 g)

Bar chart showing:
- TOCCASTAR: 3.6%
- TOCCATA: 0%

Percent Lesions with Low FTI (< 400 gs)

Bar chart showing:
- TOCCASTAR: 23%
- TOCCATA: 41%

Intra-operator Variability in CF

Bar chart showing:
- TOCCASTAR: 23.4
- TOCCATA: 17.1

Note: p < 0.0001 for all comparisons.
**WHAT IS NEXT?**

**Lesion Index: adding Power**

- **The Lesion Index (LSI™)**
  - Parameter to estimate lesion growth in real-time combining CF, ablation duration and RF current (power) information.
  - Models both electrical resistive and conductive thermal heating over time.
Lesion Index (LSI™)

- LSI: latest evolution of operator guidance towards better lesion making:
  - Force → FTI (=Force, Time) → LSI (=Force, Time, Power in complex Math model)
- Strong correlation with animal data and EFFICAS

**EFFICAS 1: Min LSI**

\[
y = 1.052x - 0.7458 \\
R^2 = 0.8069
\]

- mean error = 0.42
- mean ABS error = 0.73

**LSI calculated vs max depth measured**

\[
\text{LDI Calculated vs Lesion Depth measured [mm]}
\]

\[
y = 1.052x - 0.7458 \\
R^2 = 0.8069
\]

**LSI: guidance for Transmurality and continuity**

**LSI: Distance to next lesion**
Based on Min FTI = 400 gs, Min LSI values should be applied, even if electrical isolation is obtained before reaching these values.*

*Min LSI or until elimination of electrical signals
CONCLUSION

• Contact Force guidelines from TOCCATA, EFFICAS:
  - TARGET 20 g with range [10 g, 30 g]
  - Min > 10 g for any ablation point
  - Min > 400 gs for any ablation point
  - ONE SHOT ➔ Transmurality should be achieved in one shot

• Ongoing studies may confirm CF impact and parameters

• Prospective study needed to better define Lesion Index guidelines
PO01-133 - Application Of Contact Force Guidelines Increases Durable Isolation After Pulmonary Vein Isolation For Paroxysmal Atrial Fibrillation
Moussa Mansour, et al. (Toccastar), Mass Gen, Boston USA
Poster PO01. Featured Poster Session and Reception Wed, May 8, 6:00 - 7:30 PM

IA01-02 - Quantitative Magnetic Resonance Imaging Analysis of the Relationship between Contact Force and Left Atrial Scar Formation after Catheter Ablation of Atrial Fibrillation
Christian Sohns, MD, et al., King’s College London, UK, Endosense SA, Switzerland
Special Session SP30. Innovation Poster I. Thu, May 9, 9:30 AM - 5:00 PM

PO05-119 - Complementary Techniques And Location Of Excessive Contact Force Detection In The Left Atrium With Robotic Catheter Navigation
Sarah K. Hussain, MD, John M. Hobby, BS, David Harari, BS and J. Michael Mangrum, MD., Virginia, USA
Poster PO05. Poster Session V Fri, May 10, 2:00 - 5:00 PM


3. Neuzil et al. Electrical Reconnection Following PVI is Contingent on Contact Force during Initial Treatment - Results From the EFFICAS I Study. Circ Arrhythm Electrophysiol. 2013; 6: 327-333

4. Kautzner et al. Contact force, FTI and Lesion continuity are critical to improve durable PV isolation: EFFICAS II results. Heart Rhythm Society, 2012, Boston, USA


Complementary Techniques And Location Of Excessive Contact Force Detection In The Left Atrium With Robotic Catheter Navigation

- **Design**
  - A 3-D geometry was constructed with Ensite NavX (St. Jude Medical) using an in-vitro model of the left atrium. Four pre-designated points were marked outside the ostium of each pulmonary vein.
  - 20 operators were asked to navigate using the Sensei Robotic System (Hansen Medical) to these pre-determined points without fluoroscopy, using only the NavX geometry.
  - Proximal contact force (CF) was measured by IntelliSense technology and tip CF measured by sensor at the distal end of open-irrigated catheter (TactiCath, Endosense).
  - Each episode of excessive force (>100 g) was evaluated and the two technologies were compared.

- **Conclusion**
  - We found that IntelliSense readings correlated only with the axial component of CF, as measured by TactiCath. IntelliSense did not correlate well with overall CF, or the lateral component of CF.
  - With a total of 151 min of robotic manipulation, 33 episodes of excessive force were detected, and not all were detected by IntelliSense, as depicted in the figure.

- **Excessive CF Readings**
  - There were 33 episodes of excessive CF detected (mean 153 g): 15/33 roof, 16/33 posterior, 1/33 RSPV, 1/33 LSPV.
  - All episodes of excessive CF on the posterior wall were detected by both techniques; only 10/15 of excessive CF on the roof were detected by IntelliSense. On average, overall and axial CF were higher on the posterior wall as compared to the roof (166 vs 140 g; 143 vs 117 g).

Courtesy of Hussain SK, et al. Manuscript in Progress. – Complementary Techniques And Location Of Excessive Contact Force Detection In The Left Atrium With Robotic Catheter Navigation – PO05-119 HRS 2013