A Secure Robotics Platform for Remote Vascular Interventions

Including PCI and Stroke

Nicholas Kottenstette - R&D Fellow, Steve Blacker – R&D Fellow, Yao Li – Robotics Systems and SW Engineer II, Shenghe Zhao – Advanced Development Engineer, Todd Lander - Principal Engineer, Per Bergman – VP of R&D

Control Systems and The Quest for Autonomy
A Symposium in Honor of Professor Panos J. Antsaklis
10/28/2018

1 CorPath Systems are not indicated for neuro interventions, nor is it indicated for remote interventions.
Vascular Interventions

An overview for Coronary (PCI)

- **Vascular Interventions**
  - Physician gains access to the patient via an *introducer sheath*
  - Physician navigates *guide catheter* (GC) to opening of vascular region which requires treatment
    - Visualization is typically under X-Ray with a *fluoroscope* in which a radiopaque contrast is injected into the artery or vessel of interest in order to determine treatment options
  - Once diagnosis is complete, treatment of the vessel or artery is commenced using additional devices including
    - Micro-catheters
    - Guide wires to cross a lesion for example
    - Balloon catheters to perform *angioplasty*
    - Stent catheters to deliver a stent

- **PCI**
  - Access is typically via the radial (wrist) or femoral artery (groin)
  - Most interventions involve a GC which is seated in the left or right coronary ostium typically with the aid of a J-wire
  - Physician typically steers GW past lesion in order to allow delivery of *RX device*
  - RX device includes Semi compliant balloons for angioplasty, {bare metal, medicated} Stents, High pressure balloons for post dilatation of Stent.
  - During the procedure patient health is monitored via *Hemodynamics*
Remote Interventions

Motivation

PCI

• Time is Heart Muscle
• Reduce time to treatment in surrounding rural locations in states including:
  – Michigan (Ryan D. Madder, M.D., FACC – Spectrum Health)
  – MN (Eleid, Mackram F., M.D – Mayo Clinic)
• From 2001-2006, The number of US PCI capable hospitals increased by 44%; however, the increase of population within one hour only increased by 2%. Leaving over 20% of the US population being more than one hour from a PCI capable hospital\(^2\).

Stroke: Time to Treatment is Key

• Time is brain – Quantified, Jeffery Saver
  – Typical patients suffering large vessel acute ischemic stroke loose 120 million neurons, 830 billion synapses, and 447 miles of myelinated fibers per hour.
• Treating stroke via vascular interventions is an emerging field with improved benefits to patient outcome (~900k victims per year in US).
  – Lack of proximity to facilities (distance)
  – Limited number of specialists
    • Only 35k receiving treatment
  – Excellent opportunity for robotic intervention to increase access and reduce time to treatment.
System Overview

CorPath GRX

Key Corpath GRX Features

- Guide Catheter Control & Management
  - Prismatic and rotational motion of guide catheter allows the IC to reseat GC during complex cases when GW and/or SC pushes back due to tortuous lesions.
  - Enclosing Sheath Allows us to drive the GC distal of the patient.

- Precise monitoring and control of GW and RX devices.

- Bedside Touchscreen
  - Instructs bedside technologist through device (GW, BSC) and GC exchanges.

- techniQ™ – Rotate on Retract
  - When physicians retracts a GW due to traveling off a the main path down a child vessel, the Robodrive rotates the GW in order to adjust the tips heading and get back on the main path.

- Radiation Shield & Power Vision Monitor
  - IC remains seated at console with capacitive JS interlocking system without 25 lb of lead in order to focus on treating patient.
Permanent magnet synchronous motor (PMSM) Control

A Closed Loop Control Law of PMSMs Which Is Asymptotically Stable

PMSM is a motor in which the rotor consists of \( n_p \) in \( \{1, 2, \ldots\} \) pole pairs and stator w/ \( m \) in \( \{2, 3\} \) phases.

Assume rotor is cylindrical so the stator inductances, \( L \), are constant in the Direct Quadrature (DQ) frame.

Define electrical angle \( \theta_e = n_p \theta \), torque constant \( K > 0 \)

Park Transform:

\[
\begin{bmatrix}
    f_d \\
    f_q
\end{bmatrix} =
\begin{bmatrix}
    \cos(n_p \theta) & \sin(n_p \theta) \\
    -\sin(n_p \theta) & \cos(n_p \theta)
\end{bmatrix}
\begin{bmatrix}
    f_a \\
    f_b
\end{bmatrix}
\]

Therefore,

\[
\begin{bmatrix}
    f_a \\
    f_b
\end{bmatrix} =
\begin{bmatrix}
    \cos(n_p \theta) & -\sin(n_p \theta) \\
    \sin(n_p \theta) & \cos(n_p \theta)
\end{bmatrix}
\begin{bmatrix}
    f_d \\
    f_q
\end{bmatrix}
\]

Clarke Transform:

\[
\begin{bmatrix}
    f_a \\
    f_b \\
    f_c
\end{bmatrix} =
\begin{bmatrix}
    \frac{2}{3} & -\frac{1}{3} & -\frac{1}{3} \\
    0 & \frac{1}{\sqrt{3}} & \frac{1}{\sqrt{3}} \\
    0 & -\frac{1}{\sqrt{3}} & \frac{1}{\sqrt{3}}
\end{bmatrix}
\begin{bmatrix}
    1 & 0 & 0 \\
    0 & \frac{1}{2} & -\frac{\sqrt{3}}{2} \\
    0 & -\frac{1}{2} & -\frac{\sqrt{3}}{2}
\end{bmatrix}
\begin{bmatrix}
    f_a \\
    f_b \\
    f_c
\end{bmatrix}
\]

Define: ‘effective Q v’:

\( v_q = v_q - K \omega \)

Define: DeQ voltage: \( v_{DQ} = [v_d \ v_q] \)

Denote the DQ current as: \( i_{DQ} = [i_d \ i_q] \)

Recall skew symmetric matrix as \( S = \begin{bmatrix} 0 & 1 \\ -1 & 0 \end{bmatrix} \) in which \( S = -S^T \)

PMSM Model:

\[
\begin{align*}
L \dot{i}_{DQ} &= \ddot{v}_{DQ} - R i_{DQ} + n_p \omega L S i_{DQ} \\
J \dot{\omega} &= K i_q - \tau_l - B \omega - K_{d4} \sin(4n_p \theta) - \tau_f \tanh\left( \frac{\pi \omega}{\omega_f} \right)
\end{align*}
\]

DQ Control Law for PI Control of PMSMs

\[
\begin{align*}
e_{DQ}(t) &= i_{DQ} - r - i_{DQ} \\
\dot{i}_{DQ} - \dot{I}(t) &= k_{DQ-I} e_{DQ}(t) \\
\dot{i}_{DQ} - \dot{C}(t) &= k_{DQ-C} e_{DQ}(t) + i_{DQ} - C(t) \\
\ddot{v}_{DQ}(t) &= R i_{DQ} - C(t).
\end{align*}
\]

The proof for stability involves passivity theory showing: i) that the mapping from the PMSM voltage input \( \ddot{v}_{DQ} \) to the PMSM current output \( i_{DQ} \) is strictly output passive; ii) the PI control law (s.t. \( k_{DQ-P} > 0 \) and \( k_{DQ-I} \geq 0 \)) is strictly input passive; and iii) from the passivity theorem the resulting system is asymptotically stable.
Passivity Based Control of PSMS

Motivation

PCI
- Time is Heart Muscle
- Reduce time to treatment in surrounding rural locations in states including:
  - Michigan (Ryan D. Madder, M.D., FACC – Spectrum Health)
  - MN (Eleid, Mackram F., M.D – Mayo Clinic)
- From 2001-2006, The number of US PCI capable hospitals increased by 44%; however, the increase of population within one hour only increased by 2%. Leaving over 20% of the US population being more than one hour from a PCI capable hospital\(^2\).

Stroke: Time to Treatment is Key
- Time is brain – Quantified, Jeffery Saver
  - Typical patients suffering large vessel acute ischemic stroke loose 120 million neurons, 830 billion synapses, and 447 miles of myelinated fibers per hour.
- Treating stroke via vascular interventions is an emerging field with improved benefits to patient outcome (~900k victims per year in US).
  - Lack of proximity to facilities (distance)
  - Limited number of specialists
    - Only 35k receiving treatment
  - Excellent opportunity for robotic intervention to increase access and reduce time to treatment.

Remote Cath Lab

- Firewall with Real-Time Hardware Enabled IPSEC VPN (Gigabit, low latency)
- Simulink Real-Time speedgoat target
  - USB 3.0 based Image capture and compression of fluoro via. Magewell
  - PTP synchronization to GPS referenced Grandmaster Clock via ETH3
  - FPGA based IO for JS Console
  - High Speed CAN interface to GRX Robodrive
  - Image and C2 comm via ETH2 with IC

- Host machine
  - Console GUI for C2 via ETH1 to speedgoat
  - USB 3.0 based Image capture and compression of Hemodynamics
Remote Architecture – C2

Intervention Cardiologist (IC) Office
- Firewall with Real-Time Hardware Enabled IPSEC VPN (Gigabit, low latency)
- Simulink Real-Time speedgoat target
  - Image decompression and display of fluoro
  - PTP synchronization to GPS referenced Grandmaster Clock via ETH3
  - FPGA based IO for JS Console
  - Image and C2 comm. via ETH2 with RCL

Host machine
- Console GUI for C2 via ETH1 to speedgoat
- Image decompression and display of Hemodynamics
- Capacitative touchscreen for improved immersion and access
# Remote Technology Development

## Achievements & Planned Milestones

<table>
<thead>
<tr>
<th>Year</th>
<th>Q1 2018</th>
<th>Q2 2018</th>
<th>Q3 2018</th>
<th>Q4 2018</th>
<th>Q1 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td></td>
<td>Remote Demonstration</td>
<td>Technology Development</td>
<td>Product Development</td>
<td>First Human Use Case Initiate Remote Commercialization Process</td>
</tr>
<tr>
<td>2018</td>
<td></td>
<td></td>
<td>100 Mile Remote PCI Case</td>
<td></td>
<td>5G Pilot</td>
</tr>
</tbody>
</table>

### Videos & Presentations
- TCT 2018 Presentations
- TCT 2018 Live Cases
- Corindus Channel
For Fun : Deadlock Free Petri Net For IC and RCL C2
RCL-IC Console Petri Net

RCL without Token & IC without Token

RCL Disabled (without Token)  IC Disabled (without Token)
RCL-IC Console Petri Net

RCL with Token & IC without Token

RCL Enabled (with Token)  IC Disabled (without Token)
RCL-IC Console Petri Net

RCL without Token & IC without Token

RCL Disabled (without Token)  IC Disabled (without Token)
RCL-IC Console Petri Net

RCL without Token & IC with Token

RCL Disabled (without Token)  IC Ready to Enable All (with Token)