Design and Implementation of a Medical Robot System

Gernot Kronreif

European Surgical Robotics Demonstration Day
27/03/2014
Leuven
+ Development of new technology approaches for “Minimally Invasive Procedures“ and modern therapies in an integrative way
+ Research and innovation center for collaborative and translational research between science and industry
+ Key data:
  - 1st funding period (2010-2014): overall budget of 18MEUR
  - International network:
    25 industry partners
    27 research partners (technical + clinical)
  - Match funding
ACMIT – Integrative View

ACMIT inter-connected research areas

... "from user to treatment"
ACMIT – Integrative View

- Applied R&D → Translational R&D
  - Work-flow assessment and specification
  - Inter-disciplinary work
    - Technical development
    - Regulatory issues
    - Clinical issues
    - Market requirements
- Baseline: technology with **clinical relevance**

... "from idea to clinical use"
Disclosure

+ Integrated Microsystems Austria GmbH:
  – Producer of iSYS1 robot system on behalf of iSYS Medizintechnik GmbH, Kitzbühel, Austria

+ Gernot Kronreif:
  – Manufacturing Manager for iSYS1 production
Set-up for CT-guided Biopsies
B-Rob I - Tests CT-guided Biopsies
Review: First Prototype „B-Rob I“


Accuracy sufficient ✓
Workflow ✓
Data acquisition ✓
Review: First Prototype „B-Rob I“

Optical tracker – main source of problems (accuracy, latency, working area, line of sight)

„Stand-alone“ setup: Synchronization table – robot, (dynamic) stability

Review: First Prototype „B-Rob I“

Too complex!!
Too big!!
Too costly!!


NPU based on parallelogram ✔
Registration / Calibration for both CT and US ✔
Prototype “B-Rob II”

+ 2 x 2DOF-Modules with tool holder
  – Positioning: ± 20 mm
  – Angulation: ± 35°
  – Pivot point can be defined via HW/SW

+ Pre-positioning with 7DOF passive arm
Transfer to CE-marked system „iSYS 1“
Clinical Use

+ **Multi-centric study**
+ **Applications:**
  - RFA Trigeminus, renal
  - Biopsy spine, liver, lung
  - Multi-needle tumor ablation
  - Pain treatment L1, L3, L4 (left, right)
+ **Results:**
  - Avg. positioning error 1.21 mm at needle tip and 0.78 mm at entry point (n=21)
  - Application with robot support rated as „simpler“ (n=15) or „no effect“ (n=3)
What you should know ...

+ What are the real needs of the user?
  → Assistance for daily use!

+ Clinical relevance?

+ Cost vs (clinical) benefit?
  → Refunding option?

+ Right partners?
  → Interest of the partner(s)
It is more than just „functioning“!

+ **Demonstration of clinical benefit**
  - Demonstration in clinical evaluation ↔ device already product
  - Task specific design or universal device?

+ **What else?**
  - Human factors
    - Impact of new technology to existing structures and processes
    - Usability, Intuitiveness
  - Interfaces to existing setup and procedures
  - “Life cycle” of the device
  - Economic constraints
    - New technology resulting in higher cost?
    - Is it possible to have any additional cost refunded?
    - Is the device yet profitable for manufacturers?
What makes a medical technology successful?

Successful setup depends on four criteria:
- Device must provide quantifiable, functional benefits to the patient.
- Device should improve the efficiency of physician’s current practice.
- Device should be affordable for clinics yet profitable for manufacturers.
- Device should not increase the cost of health care.

\[\text{COST} < \text{PRICE} < \text{BENEFIT}\]
Some of the „Lessons Lerned“, Ctd

+ Look for applications and procedures that benefit from a new (robotic) solution!
+ How to demonstrate clinical benefit and cost reduction?
+ Integration
  – into existing hardware
  – into existing workflow
+ Complete setup rather than „component“
+ Time of intervention (also including setup time!) must not be increased!
Some of the „Lessons Lerned“, Ctd

+ „KISS“ -- Keep it simple, stupid
  – The more functions the system have the more can go wrong
  – Complexity doesn‘t help during certification
  – Ease of interaction is key!
  – Complexity of setup must be considered!
Some of the „Lessons Lerned“

+ The later you change your design, the more expensive it will be
  – Careful selection of external components and suppliers
  – Extensive evaluation is key!
  – Evaluate system under real clinical requirements ASAP!
  – Clear separation between research and production phase

![Graph showing the relation between level and ease of change over time: Early, Middle, Late. The graph indicates that the level decreases as the ease of change increases.](image-url)
Some of the „Lessons Lerned“

+ **Set up the right team and infrastructure**
  
  – Good researchers are not (necessarily) good product developers!
  
  – Don’t underestimate the problems of (mass) production
  
  – Additional competences required (quality manager, regulatory affairs manager, product manager)
Thank you!

ACMIT
Viktor Kaplan-Straße 2
2700 Wiener Neustadt, Austria
Tel.: +43 (0) 2622-22 859-0
Fax: +43 (0) 2622-22 859-55
www.acmit.at
Gernot.Kronreif@acmit.at