A novel platform for Scarless Robotic Surgery: the ARAKNES (Array of Robots Augmenting the KiNematics of Endoluminal Surgery)

Integrating Project

ARAKNES Project Coordinator
Prof. Paolo DARIO
Scuola Superiore Sant’Anna
Pisa, Italy

www.araknes.org

The ARAKNES (Array of Robots Augmenting the KiNematics of Endoluminal Surgery) Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.
Outline

- Motivations and strategy
- A novel platform for Scarless Robotic Surgery: the ARAKNES Project
  - Objectives
  - Key results
  - Progress status
- ARAKNES first prototype
  - Progress status and current work
- Research platform
- Industrial exploitation
Motivations and strategy
A novel platform for Scarless Robotic Surgery: the ARAKNES Project
  – Objectives
  – Key results
  – Progress status
ARAKNES first prototype
  – Progress status and current work
Research platform
Industrial exploitation
Convergence to Computer Assisted and Robotic Surgery

Modern surgery

Minimally invasive surgery

- Shorter recovery time
- Lower risk of infection
- Less pain/trauma for the patient
- Shorter hospital stay/reduced cost

Computer-assisted surgery

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011
The “Da Vinci” System
The “Da Vinci” System

+ Stereoscopic tridimensional visualization
+ Dexterity
+ Motion scaling
+ Extremely successful (1500+ systems in operation worldwide. The Gold Standard in prostatectomy and hysterectomy)

− The Da Vinci surgeon console is immersive, thus preventing the user to perceive what is going on in the operative room
− Four 12-mm diameter accesses (3 for the instruments and 1 for the camera) and an additional 5-mm service access are required
− Very expensive (1.5 – 2.5 M€ system, plus disposables and servicing)
The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011
NOTES & SPL

Reduction, or even total elimination, of visible scars

Natural Orifice Transluminal Endoscopic Surgery (NOTES)

NOTES is an experimental surgical technique whereby "scarless" abdominal operations can be performed with an endoscope passed through a natural orifice (mouth, urethra, anus, etc.) then through an internal incision in the stomach, vagina, bladder or colon, thus avoiding any external incisions or scars.

Single Port Laparoscopy (SPL)

SPL exploits a single incision that can be performed underneath the umbilicus, thus taking advantage of an already existing scar.

Applying robotics to NOTES and SPL may be, in our opinion, the next frontier for robotics surgery.

Both procedures are currently performed with standard endoscopic or surgical instrumentation, while ad hoc technical solutions are not yet fully developed.
Recent trends:” Intuitive” SPL

Current development by Intuitive Surgical, Inc.

- Using da Vinci Si system with 8.5mm 3D HD endoscope.
- Curved Instrument Cannulae.
- 5mm, non-wristed, semi-rigid instruments.

- New instruments for old platform
- Limiting incisions
- Research SPL robot

Instruments and accessories not yet approved by FDA
Outline

- Motivations and strategy
- A novel platform for Scarless Robotic Surgery: the ARAKNES Project
  - Objectives
  - Key results
  - Progress status
- ARAKNES first prototype
  - Progress status and current work
- Research platform
- Industrial exploitation
Array of Robots Augmenting the KiNematics of Endoluminal Surgery

PARTICIPANTS

<table>
<thead>
<tr>
<th>PARTICIPANTS</th>
<th>COUNTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scuola Superiore Sant’Anna</td>
<td>SSSA</td>
</tr>
<tr>
<td>Imperial College London</td>
<td>ICL</td>
</tr>
<tr>
<td>Università di Pisa</td>
<td>UNIPI</td>
</tr>
<tr>
<td>Ecole Polytechnique Fédérale de Lausanne</td>
<td>EPFL</td>
</tr>
<tr>
<td>MicroTech S.r.l.</td>
<td>MT</td>
</tr>
<tr>
<td>KARL STORZ GmbH &amp; Co. KG</td>
<td>KST</td>
</tr>
<tr>
<td>ST Microelectronics</td>
<td>STM</td>
</tr>
<tr>
<td>School of Physics and Astronomy, University of St. Andrews</td>
<td>USTAN</td>
</tr>
<tr>
<td>University of Barcelona</td>
<td>UB</td>
</tr>
<tr>
<td>Laboratory of Computer Sciences, Robotics and Microelectronics, Centre National de la Recherche Scientifique</td>
<td>CNRS</td>
</tr>
<tr>
<td>novineon Healthcare Technology Partners GmbH</td>
<td>NVN</td>
</tr>
</tbody>
</table>

Start Date: May 1, 2008
Duration: 4 years
Total Budget: 11.100.000 €
EU Contribution: 8.100.000 €
From dream to reality

**VECTOR project** - Single capsules with limited intervention capabilities

**ARAKNES project** - Reconfigurable endoluminal structures for endogastric and abdominal interventions

**ARES project** - Reconfigurable assembling capsules for endogastric interventions

Clinical platform

Research platform
The ARAKNES Vision: Bringing the Operating Room Inside the Patient

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011

- Grasper
- Needle Holder
- Retractor
- Biochemical and Optical Probes
- Emostatic sponges
- Suction/Irrigation
- clip Applier
- Endobag
- Ultracision
- Vision
The ARAKNES Clinical System

Design of the surgical scenario and of the system architecture, including all the main components of the system and the definition of the main control scheme of the ARAKNES platform

- Autostereoscopic Display
- Additional Displays
- User Console
- Bimanual Controller
- ARAKNES robotic unit for umbilical access
- ARAKNES robotic unit for oesophageal access
- Patient Support System
System Design

Fault Manager

Controller (WP7)

Motor commands

Registered imaging data

Commands (robotic platform, cameras, biosensors)

Pre-Operative Data (WP8)

Haptic and position feedback

Images for visual servoing

Motor and Camera commands

Motor and position commands

Registered imaging data

Camera control

Pump control

Motor commands

Insufflation pump (WP4)

Insertion Port (WP4)

Panoramic Camera (WP6)

Physiological sensors (WP5)

Optical Characterisation Modules (WP5)

Position sensors

Stereoscopic Camera (WP6)

Robotic Platform (Internal Unit) (WP4)

Robotic Platform (External Unit) (WP4)

Sensors

Encoders & other sensors

Motor commands

Pression information

PATIENT

PATIENT SUPPORT SYSTEM (WP8)

Controller

Table commands

Display

Controller

Filter (WP5)

Controller for Optical Characteris (WP5)

Tissue information

Stereoscopic Vision feedback

Tissue Information

Surgeon

WP8 CONSOLE
The ARAKNES Project has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011

ARAKNES Prototypes

- Console
  - ICL
- High Level Controller
  - CNRS
- SAFETY
- Validation
  - Endocas
- Bi-manual Robot + Controller
  - SSSA
  - STM
  - EPFL

Motor commands

Pump control

& other sensors

Images for

Motor and camera commands

Insertion Port (WP4)

Panoramic Camera (WP6)

Stereoscopic Vision feedback

Controller for Optical Characteristics (WP5)

Panoramic Vision feedback

Table commands

Controller

PORT SYSTEM (WP8)
Outline

- Motivations and strategy
- A novel platform for Scarless Robotic Surgery: the ARAKNES Project
  - Objectives
  - Key results
  - Progress status
- ARAKNES first prototype
  - Progress status and current work
- Research platform
- Industrial exploitation
The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011

The ARAKNES External Manipulator

...moving the INTRODUCER using an industrial robot:

Work in progress: workspace analysis of the SPRINT DOFs + INTRODUCER DOFs

6+6+2 DOF + 6 DOF = 20 DOF
The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Wrist

- Embedded electronics
- 3 DOFs wrist for total 6 DOFs + gripper
- Cable-driven gripper, actuated by external Faulhaber motor 20W
Micro- & Nano-Systems for Endoluminal Monitoring & Therapy

Array Fabrication

1) Pins insulation
2) Pins drying
3) Pins polishing
4) Ag and Pt electrometallization

Structural information from Optical Coherence Tomography (OCT)

Biochemical information from Raman spectroscopy

Physiological information from backscattering

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011
Optical System Development

Image acquisition systems

- Vision system for access ports
  - Flexible Oesophageal access port (MT)
    - Fixed panoramic vision system (KST)
      - Fully integrated in tube wall (MT)
      - HD-resolution
      - 2D
      - Light guiding fibers
  - Rigid Umbilical access port (SSSA)
    - Fixed stereo vision system (KST)
      - Fully insertable in the umbilical access port (SSSA)
    - Steerable stereo vision system (SSSA)
      - Fully insertable

- Vision system for robotic modules
  - Steerable stereo vision system (SSSA)
    - Steerable stereo vision module (EPFL)
      - Compact solution
      - Connected to external actuators
      - Pan and Tilt DOFs
      - 3D
  - Fixed stereo vision system (SSSA)
    - Fixed panoramic vision system (KST)
      - Fully integrated in tube wall (MT)
      - HD-resolution
      - 2D
      - Light guiding fibers
Outline

- Motivations and strategy
- A novel platform for Scarless Robotic Surgery: the ARAKNES Project
  - Objectives
  - Key results
  - Progress status
- ARAKNES first prototype
  - Progress status and current work
- Research platform
- Industrial exploitation
Two robotic manipulators and a camera

15 mm umbilical port

Magnetic coupling with an external magnet held by industrial robotic manipulators

Increased workspace (no entrance constraints) and dexterity

3 mm needle for retraction
Outline

- Motivations and strategy
- A novel platform for Scarless Robotic Surgery: the ARAKNES Project
  - Objectives
  - Key results
  - Progress status
- ARAKNES first prototype
  - Progress status and current work
- Research platform
- Industrial exploitation
ARAKNES Exploitation Plan (EP)

- The *ARAKNES EP* is based on the evaluation of any possible industrial or commercial applications and on the analysis of the potential both of the entire ARAKNES platform and of derivative devices.

- The *ARAKNES* Consortium is pursuing a stepwise approach in exploiting the Project results, consisting of:
  - Business Plan BP development assisted by industrial partners
  - Continuous monitoring of potential competitors including IP situation and generation of a patent portfolio
  - Continuous monitoring of new potential applications for the ARAKNES Platform and for its single modules
  - Successful development and assessment of the different derivative devices
  - Market evaluation and testing by presentation of project results and demonstrations during relevant medical congresses
  - Generation of concepts for the transfer of project results in products or product-components
  - Continuous updating of a market analysis
Most Promising Derivative Devices

- Optical system for Endoscopy based on OCT, Raman and backscattering

- Electrochemical sensor for surgical procedure monitoring

- Camera (mono and stereo) with magnetic levitation for abdominal surgery

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011
Raman Lab-on-a-chip: Waveguide Confined Raman Spectroscopy

a) Microfluidic device for bioanalyte detection

b) Region of Raman signal detection

c) Photograph of the collection region
e-Sensor Development

Development of electrochemical multi-sensor array for monitoring ischemia in situ and in vivo in stomach tissue

- Array fabrication:
  - Metallization
  - Characterization

- Sensor development:
  - pH sensor test on the prototype

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011
The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011

Levitation Camera Robot

- Equilibrium between a magnetic internal mechanism and elastic flexible joint allows for camera levitation → tilt spanning angle $0^\circ - 80^\circ$
- External diameter: 12 mm → introduction through a standard 12 mm trocar for Laparoscopy or LESS surgery
- Enabling multiple points of view
- No need for a dedicated port
<table>
<thead>
<tr>
<th>Owner</th>
<th>Name/application</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSSA</td>
<td>“ARAKNES 1-Ibrido”, Italian Patent FI2010A000075,</td>
</tr>
<tr>
<td>SSSA</td>
<td>“ARAKNES 2-Introduttore”, Italian Patent FI2010A000076, registered on 26/04/2010</td>
</tr>
<tr>
<td>SSSA</td>
<td>“ARAKNES 3-Pulegge”, Italian Patent FI2010A000077, registered on 26/04/2010</td>
</tr>
<tr>
<td>SSSA</td>
<td>“Capsula MIM”, Italian Patent FI2009A000150, registered on 08/08/2009. (SSSUP)</td>
</tr>
<tr>
<td>USTAN</td>
<td>“Optical Backscattering Diagnostics”, filed in the UK on: 09/04/ 2010</td>
</tr>
<tr>
<td>USTAN</td>
<td>“Monolithic device”, Filed in the UK on: 9 April 2010</td>
</tr>
</tbody>
</table>
Field of application: Single-port access laparoscopy, transluminal bariatric surgery (both with restrictive procedures and malabsorptive procedures) cholecystectomy (a de facto benchmark for surgical devices)

Background: DaVinci robotic system

Clinical Advantages: less bulky, thus avoiding the isolation of the surgeon during the procedure, Operative Room inside the patient, less incisions

Technological advantages: enhance the capabilities of the surgeon many DOF, SILS robot

Intellectual property: the device is covered by patents
IT-FI20100075 CLAIM 1

Robotic arm (101, 102; 201, 202) especially suited for minimally invasive surgery operations, in particular laparoscopic surgery, comprising a torsional joint (6) and a flexural joint (5) serially arranged, said joints (5, 6) providing respective degrees of freedom for said arm,

- said robotic arm receiving, or being capable to receive drive means (38, 39) for said flexural (5) and torsional (6) joints,
- said robotic arm further comprising transmission means (340, 350, 34-36) placed between said drive means (38, 39) and said joints (5, 6),
- wherein said transmission means comprise a first (340) and a second (350) assembly of three gear wheels, preferably of the conical type, and a train of three additional gear wheels (34-36) preferably straight-cut gear wheels, which couple said first (340) and second (350) assembly to form a differential mechanism.
The ARAKNES Project has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

SPRINT IP
IT-FI20100076

CLAIM 1
- Robotic apparatus for minimally invasive surgery operations (100) in particular laparoscopic surgery, comprising:
  - at least an articulated arm (101;201) having a plurality of degrees of freedom and capable of performing manipulatory tasks in surgery;
  - an introducer body (103;603) insertable through the patient skin to create an access port to a surgical site, said introducer body (103;603) having an inner longitudinal duct, said inner duct having a proximal inlet section and a distal outlet section and being configured for allowing the passage of said articulated arm (101;201) through said introducer body (103;603); and
  - locking means (115,117;608) for making integral a proximal part (111;121;131) of said articulated arm (101;201) to said introducer body (103;603).

EPO SEARCH REPORT
SPRINT On-going BP(2): Development Status

SPRINT 1.0 Proof of concept prototype:
- developed and tested with surgeons
- analysis of regulation aspect:
  - motors class of electrical protection IP67
  - sterilization: Maxon and Faulhaber electrical motors are not autoclavable for the dimensions needed
  - materials fatigue

SPRINT 2.0 Prototype under development with improvement towards industrialization of the robot:
- disposable vs reusable system/components
- new kinds of actuation for easier sterilization and cleaning
- enhanced reliability and accuracy
- plastic components
- reduction of production costs
SPRINT On-going BP(3): Market Analysis

Market Size:
- number of possible interventions from national and international DRG (diagnosis related group) from ministry of Health database
- comparison with DaVinci data

Target Customer:
- Private public Hospitals
- Training centers

Production Costs:
SPRINT 1.0: 200,000 € (difficulties in sterilization aspects)
SPRINT 2.0: Target 100,000 €
### SPRINT On-going BP(5): Comparison with competitors

<table>
<thead>
<tr>
<th>Robotis System</th>
<th>For SILS</th>
<th>DOF</th>
<th>Force feedback</th>
<th>Size</th>
<th>Central auxiliary lumen</th>
<th>Price</th>
<th>ON THE MARKET</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITAN</td>
<td>NO</td>
<td>12</td>
<td>YES</td>
<td>Bulky</td>
<td>No</td>
<td>---</td>
<td>NO</td>
</tr>
<tr>
<td>ALF-X</td>
<td>NO</td>
<td>12</td>
<td>YES</td>
<td>Bulky</td>
<td>No</td>
<td>---</td>
<td>NO</td>
</tr>
<tr>
<td>MIROSURGE</td>
<td>NO</td>
<td>12</td>
<td>YES</td>
<td>Bulky</td>
<td>No</td>
<td>---</td>
<td>NO</td>
</tr>
<tr>
<td>INTUITIVE DAVINCI</td>
<td>NO</td>
<td>21</td>
<td>NO</td>
<td>Bulky</td>
<td>No</td>
<td>2.5 MIL €</td>
<td>YES</td>
</tr>
<tr>
<td>INTUITIVE SILS ADAPTED</td>
<td>YES</td>
<td>12</td>
<td>NO</td>
<td>Bulky</td>
<td>No</td>
<td>200.000 kit +2.5 MIL</td>
<td>NO</td>
</tr>
<tr>
<td>INTUITIVE SILS</td>
<td>YES</td>
<td>?</td>
<td>?</td>
<td>Small</td>
<td>No</td>
<td>?</td>
<td>NO</td>
</tr>
<tr>
<td>ARAKNES SPRINT 1.0</td>
<td>YES</td>
<td>20</td>
<td>NO</td>
<td>Small</td>
<td>Yes</td>
<td>500.000 €</td>
<td>NO</td>
</tr>
<tr>
<td>ARAKNES SPRINT 2.0</td>
<td>yes</td>
<td>27 *</td>
<td>YES</td>
<td>Small</td>
<td>Yes</td>
<td>Target 350.000 €</td>
<td>NO</td>
</tr>
</tbody>
</table>

* 3 ARMS WITH (6+1) DOF EACH + 6 DOF EXTERNAL MANIPULATOR

---

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011
SPRINT 1.0 On-going BP(5): Operational Plan

Manufacturing and Outsourcing:
- MAXON motors, Fahulaber, ST microelectronics for SPRINT 1.0
- Enki srl, Medical tubing MicroSpec Inc. for microtubes
- Makuta technics, Sovrin and MTD micromoulding for injection moulding of microparts
- Dover, Armak, TKD for SPRINT 2.0 actuators

Regulatory issues:
- IEC 62304 Medical device software - Software life cycle processes
- UNI EN 2007/47 Medical Device Directive
- UNI EN CEI ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- UNI CEI EN ISO 14971 Medical devices -- Application of risk management to medical devices.
**ARAKNES Project**

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.

Concertation and consultation workshop on Micro-Nano-Bio Convergence Systems 2011

---

**Estimated overall cost:** from 10 to 20 mil. €

**Estimated trials cost:**
- from 200 to 500 k€
- from 2 to 3 mil. €

**Preclinical (safety and effectiveness)**
- Bench testing
- Animal testing

**ARAKNES System: Road to Market**

**2011**
- ARAKNES pre-industrial prototype
- JOC

**2012**
- ARAKNES industrial prototype
- Funding search

**2014**
- Production of first lot
- Investors

**2015**
- Production of series
- Investors
- Distribution

**2016**
- 106 interventions/year in EU
- Market

**Continuous Monitoring of Business Plan**

**ARAKNES System: Road to Market**

**Preclinical (safety and effectiveness)**
- Bench testing
- Animal testing

**First pilot trials**
- Phase I (mono-centric)
- 20-50 patients

**Pivotal trials**
- Phase II (multi-centric)
- Min. 20 patients per kind of intervention

**Patient Monitoring and data collection**
- Phase III trials

**industrialization**

**production**

**Estimated trials cost:**
- from 200 to 500 k€
- from 2 to 3 mil. €
SPRINT Robot: First Test Sessions with Expert Surgeons

- Tests on first working prototype:
  - individuation of problems and opportunities
  - specific feedback

- Survey to surgeons:
  - slightly good results
  - the system has to be improved in the control but the idea is seen as disruptive
  - additional surgical instruments and several aspects have to be considered and designed to have the real medical device but we are on the way for it

Test results
Test Sessions with Expert Surgeons

The ARAKNES Project has received funding from the European Community’s Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 224565.
Final Remarks
www.araknes.org

- Two platforms (clinical and research) identified
- Two different teams with different missions (strong synergy ensured by the Coordinator)
- Two types of measurable objectives (papers, patents, clinical devices)
- Reducing risks by eveloping not only integrated systems but also derivative devices
- Working continuously together with expert users (i.e. surgeons), getting feedback and incorporating feedback in new designs
- Attention to IP protection, competitors, market
- Now in the phase of refining business models and looking for interested industrial partners (internal to the Consortium, external to the Consortium, for the system, for the derivative devices, creating start-ups, etc.)