Towards a metadata registry for evaluating Augmented Medical Interventions

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Augmented Medical Interventions

Augmented surgery in Grenoble: a serie of premieres

1989: Robotized Brain Stereotaxic Surgery
S. Lavallée, Pr. A L Benabid

1995: Navigation of Orthognatic surgery
Pr. B. Raphael

1997: Navigation of Knee Ligamentoplasty
Dr. R. Juilliard

1999: Navigation of Total Knee Prosthesis
Pr. D. Saragaglia

2000: MRI/sonography fusion for prostate curietherapy
Pr Bolla, Dr Fourmeret, J.Y. Giraud, Pr Descottes

2003: 2006

Network of spin offs
Collaboration with TIMC-IMAG laboratory and Grenoble hospital
Drug Evaluation

1) Randomized & double-blind clinical trial

Drug to be evaluated
Placebo / reference

2) Observational studies / registries

Expected Medical Benefit

Post market surveillance
Medical device evaluation

Why is it specific?

• **Methodology**: 
  Randomized trial may be difficult, double-blind trial may be impossible, selection bias, innovation is unstable, judgment criteria?, lesser culture of clinical trial

• **A MD is not a drug!**: 
  *The clinical effect of a drug is not directly dependent on the skill of the prescriber* [Koustam 2003]

Our approach: modelling for the evaluation!

Modelling for the determination of relevant concepts allowing us to evaluate the use of the medical device in practice

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Our work hypothesis

The medical device use Patient’s clinical parameters
Example: ACL navigation (1/4)

Posterior view of the right knee

Positions of the tunnels and laxities estimated during surgery thanks to knee modelling

Positions of the tunnels and laxities estimated from scanners before surgery

ACL rupture

Skiing, ...

Hyperlaxity of knee

Goal: to decrease laxities

ACL surgery

ACL navigation

Plaweski, 2008

Anne-Sophie Silvent
Modelling of an ACL navigation (2/4)

Data source

One surgery : One CD with log file
79 CDs

These data have never been exploited for modelling surgery and thus, have not been designed for this goal!
Modelling of an ACL navigation (3/4)

Extract from a log file of the application monitor. Currently, the format is txt.

Raw metadata

Data Organisation & modelling

Installation
Calibration
Acquisition
Modelling
Pre nav
Navigation
Post nav

Total time of the surgery

Y axis represents a super state that comprise few states encoded by numbers in the graph.
Modelling of an ACL navigation (4/4)

**Information Extraction**
What quantitative criteria for describing surgical procedure?

**Inference analysis: knowledge discovery**
Is there a link between a linear procedure and clinical data?

![Box plot showing comparison between pre-navigation and post-navigation laxities for linear and non-linear procedures.](chart)

1) Non significative difference in term of laxities reduction
2) SIGNIFICATIVE difference in term of pre-navigation laxities

→ Would a surgery on patient with small laxities be more complicated?

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Discussion & perspectives

1) ACL logs are based on a first knowledge modelling and have high informative potential but incomplete (debug!)

→ in course: Explicit knowledge modelling with super states (XML format)

1) Hierarchy

2) Terminology and proprieties for each level

2) To do: Generalization and validation with others clinical navigated applications (→ augmented surgery knowledge domain)
Perspectives

Collection data project:

- Partners: Hospital, Research laboratory and several spin offs (~10),
- Confidentiality Agreement in progress (industrial propriety, …): performance/openness duality with industries
- Consortium agreement in september (compliance with the law on collection on health personal data, …)

→ a representative point of view in our field (knowledge base?)

Collection data project: metadata registries

Concept/prototype → CE mark → Expected Medical Benefit

2007/47 CE
Post market clinical follow-up

The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance
Acknowledgements

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- **Pr JL Bosson, Dr S. David-Tchouda** (CIC of Grenoble): methodologists

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Thanks for your attention!