



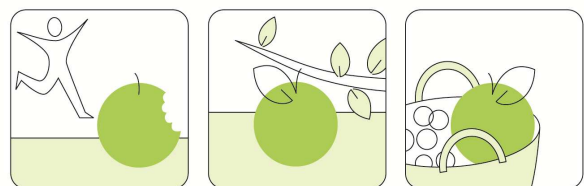
**EU Public Health Outcome Research and Indicators Collection
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Data Mining and Arthroplasty Register datasets

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Background:

This document is prepared by Gerold Labek based on information and publications by Kerstin Pankewitsch. The main reference is the PhD-Thesis of Mrs. Pankewitsch of the Martin-Luther Universität Halle-Wittenberg, Wirtschaftswissenschaftliche Fakultät, Institut für Wirtschaftsinformatik und Operations Research submitted in 2004 with the title:

Modell zur Bestimmung des optimalen Revisionszeitpunktes in der Hüft- und Knieendoprothetik

Data and results have been published in oral presentations at the EFORT-Congress 2007 in Florence (Pankewitsch K, Havelin LI, Furnes O, Espehaug B, Steindal K, Fenstad AM, Klima S, Labek G, Sprengel C. Modern methods of Data Mining for arthroplasty registers – single analyses, periodic analyses, and predictions - Based on data from the Norwegian Hip Arthroplasty Register from 1987 to 2005. 8th EFORT Congress Florence, 11.-15. May 2007.)

Aim of this research project was to study advanced mathematical models to increase risk detection in arthroplasty registers.

Subject of the study was the question whether it is possible to transfer risk calculation models from high risk technical procedures like aircrafts or atomic plants to the high risk field of medicine, particularly arthroplasty.

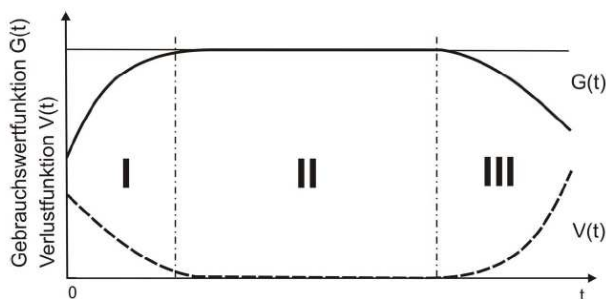


Abb. 3: Verlauf von Gebrauchswertparameter und Verlustfunktion

(Quelle: Lauenstein, G. et al., 1993, S. 22)

In general the risk of failure is not a linear function, but is following definable curves, starting with a phase I with increasing function followed by phase II with stable quality. After some time the value is decreasing for example due to wear leading to failure. Each phase requires specific monitoring. At present the follow up intervals are done in general annually. In consequence in phase II at pain free patients a relevant number of controls are performed in an uneconomic way.

In Germany the expenses of 10 years of follow up controls of patients, who received an artificial joint implant in one year, is in total 850.000.000€.

By a risk adjusted procedure the costs are calculated with 300.000.000€. It would be possible to save money in the public health sector in reasonable amount by risk adjusted follow up procedures. Implants without outcome data to calculate risk like new implants on the market or implants with identified increased risk would require more frequent monitoring than implants with well known outcome as the patient is free of pain.

This hypothesis was tested in cooperation with the Norwegian National Arthroplasty Register. The methodology including software was developed in Halle/Saale and was tested on real Register data in Bergen, Norway.

Results:

The test phase was completed successfully. It was possible to identify risk factors in short time with high predictability and sensitivity in retrospective data analyses of known inferior outcome of medical devices like Boneloc (ref. technical report # 9).

It is possible to calculate risks for every reason of revision, representing specific reasons of failure in single, periodic and supplementary analyses. By this analyses it is possible to identify most relevant attributes leading to specific prediction of survivorship. This methodology can be used referring to the indicator revision rate submitted to ECHI by EUPHORIC.

It is also possible to calculate the performance of individual medical devices with adjustment to individual influence factors and failure mechanisms in order to identify factors leading to inferior outcome. This can be used for actions to solve the identified reasons of failure.

The methodology potentially can be used to calculate economic effects of reactions like introducing products into the market or the choice of individual implants.

This might be included in assessments to achieve optimal solutions.

Basic for calculations are reliable comprehensive datasets quality level A.1.1.1 according to the classification developed in EUPHORIC (reference: Main document Orthopaedic pilot, page 64).

Summary:

- Data mining and other advanced mathematical procedures would be able to contribute to the quality of Arthroplasty Register Reports concerning sensitivity as well as concerning predictability.
- Further research and projects to develop advanced evaluation methodologies based on a common standard would be useful in order to set up a standardised reporting system for outcome measurement and market monitoring.