Indirect performance indicators as often neglected criteria in decision making – a case study for spinal interbody fusion implants, using biomimetic technologies

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Indirect performance indicators as often neglected criteria in decision making – a case study for spinal interbody fusion implants, using biomimetic technologies

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Introduction

To assess the effectiveness of medical technology or medical devices, decision-makers evaluate these services or products by means of indicators. These indicators exist in a wide variety of categories.

First, however, indicators derived from the relevant regulations and guidelines (MPG / MDR) must be mentioned for medical technology or medical devices. These indicators apply to all medical products and are defined, summarized and evaluated in two categories: (1) safety and (2) performance. The safety and performance indicators are derived from the intended purpose, the product specifications, risk management, usability, and from the Medical Device Regulation (EU) 2017/745, Annex 1. In addition, these forementioned indicators, there are also financial, economic, and sociopolitical indicators for each product. This is the case for all medical technology products and applies in particular to implants in this particular case study with “spinal (interbody) fusion devices”.

Regulatory and financial indicators are generally considered to be direct performance indicators. Socioeconomic indicators are usually discussed as indirect performance indicators. While direct indicators are often readily identifiable, identifying indirect indicators requires a precise analytical approach, detailed knowledge of the ecosystem, as well as the healthcare system in which the medical devices are used, invoiced and reimbursed.

While the determination of regulatory performance indicators is the responsibility of developers and regulatory experts, financial specialists optimize financial performance indicators. For the verification of indirect performance indicators, discussion with health economists is recommended. In order to evaluate a medical device with regard to all its performance indicators, a multidisciplinary approach is required in any case and should be considered in the decision-making process of stakeholders and economic operators, such as purchasing departments and/or - associations, healthcare insurance companies, politicians and other decision makers.

Material and Methods

The reference product for the determination of indirect and direct performance indicators is a vertebral body fusion implant with associated instruments for the treatment of the diseased spine, developed by a R&D start-up (stimOS GmbH, Constance, Germany), which does not differ in geometry and clinical application from the "golden standard", but is characterized by the following innovative features, which may

have a direct influence on the indirect indicators of the product as well:

(1) spineFuse^{MBT} interbody fusion implant made of PEEK manufactured in the MBT 3D-open-porous process (implant class IIb: classification according to MDR, Annex VIII).

(2) mimicking bone implant topography created in the MBT 3D-open-porous process for improved anchorage and healing of the implant.

(3) first bio-chemically covalently bonded porous surface functionalization of the implant for accelerated healing and prevention of inflammatory reactions.

Product description

These spineFuse^{MBT} 3D open-porous implants are spinal interbody fusion implants. The clinical use and the principle of operation of interbody fusion implants are well-known and the clinical benefit sufficiently proven. For these evaluations, Posterior Lumbar Interbody Fusion (PLIF) and Anterior Cervical Interbody Fusion (ACIF) implants were used, and their surgical methods are considered as "golden standard surgical techniques" for the treatment of degenerative spine diseases.

SpineFuse^{MBT} 3D open-porous implants, developed by stimOS GmbH are characterized by their stealth technology. Stealth technologies refer to the implant properties that help to ensure that the implant is not recognized by the patient's body as a foreign material, but rather as "the body's own" material. The specially developed stealth function of the implant is achieved through the interaction of various factors while maintaining proven geometries.

Design and development features

Although the case study presented in below paragraphs describes spinefuse^{MBT} implants, the experience gained can also be applied to all surgical interventions, where improved osseointegrative material properties of the implant are desired.

In the following, the authors will limit themselves to the market analysis of interbody fusion implants, specifically in the manufacturers domestic market, Germany.

Ideally, implants are defined by (a) geometry, (b) material properties, (c) surface function and (d) manufacturing process.[1]

While the (a) geometry of interbody fusion implants and the surgical method (Surgical Technique) has been improved and refined over decades towards more minimally invasive surgery, implants currently available on the market have significant weaknesses in (b) material properties, (c) surface function and (d) manufacturing process. However, topics (b), (c) and (d) have a significant influence on treatment costs, the healing process and the patient's quality of life, after surgery (indirect indicators).

spineFuse^{MBT} implants rely on proven implant geometries and surgical methods, but have consistently improved topics b, c, and d. The interbody fusion implants can be used according to proven surgical techniques, yet combine additional, positive properties of different approaches, manufacturing processes and surface functionalization technologies in one implant: spineFuse implants combine a polymer core (implantable, certified PEEK) with a bone-identical surface mineralization (ISO 13485 validated Mimicking Bone Technology) in a 3D-open-porous manufac-turing process to enable a bone-like micro structured and porous implant surface.

Determination of direct performance indicators

Direct indicators, such as safety and performance indicators, result from the implemented development concept, the

[1] MedDEV Quarterly, II/2019

safety and performance requirements of the MDR, Annex VIII, and the risk assessment. These indicators include improved healing of the implant, prevention of Post-OP infections, accelerated formation of new, healthy bone, preservation of healthy parent bone, and stable bone formation after implant use.

These performance indicators have been demonstrated by the company through verification and validation measures that include comparative cell tests performed by the University of Konstanz, a comparative animal study performed by Vetsuisse, University of Zurich and Charité Universitätsmedizin Berlin - approved by the Veterinary Office of the Canton of Zurich - as well as by means of the mandatory ASTM mechanical tests.

Financial performance indicators have afterwards been derived from the brochure of the developing company, which describes the selling price of the innovative implants as "comparable to the cost of conventional implant systems".

Healthcare-system background of the case study

The 12-month prevalence of chronic low back pain in Germany, defined as "back pain lasting three months or longer, and almost daily," was 16% in men and 22% in women, and lifetime prevalence was 24% and 30%. Back pain (regardless of duration and severity) in the past 12 months was reported by 57% of men and 66% of women, and back pain on the previous day was reported by 18% of men and 27% of women.[2]

Patients with chronic low back pain have significantly more frequent comorbidities: It could be shown that, the higher the stage of chronic pain, according to the MPSS (Mainz Pain Staging System), the higher the number of additionally disturbed organ functionality, these patients suffer from.

Furthermore, Higher scores for depression and anxiety for people with chronic back pain have been documented. So, with that known, Psychological comorbidity should also be taken into account, in its diagnosis and treatment of acute and chronic specific spinal diseases, especially before the indication to undertake any form of surgical measures.[3]

Advantage of the medical technology solution and determination of indirect performance indicators

Expenditures for the treatment of low back pain, burden the German population and health insurance funds with over 49 billion euros per year, corresponding to about 1.5% of the German GDP.

- 7% of patients cumulatively account for 80% of the costs. These 38 billion euros represent specific-surgical treatments and invasive solutions.
- Associated with low back pain, the Federal Statistical Office reports an average of 91.3 days of sick leave.
- 81% of patients undergo rehabilitation, additional treatments, alternative therapy or revision treatment after successful treatment.[4,5].

The scientific institute of the AOK as well as the Federal Office of Statistics report about 15% necessary reoperations (per year) due to infection, inflammation or implant

[2] H. Neuhauser, U. Ellert, T. Ziese; Chronic Back Pain in the General Population in Germany: Prevalence and Highly Affected Population Groups; Thieme Verlag Stuttgart 2003

[3] Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC); S2k-Leitlinie: Spezifischer Kreuzschmerz; AWMF Registernummer: 033-051; 2017

[4] Annette Becker, et al.; Low Back Pain in Primary Care: Costs of Care and Prediction of Future Health Care Utilization; Spine Vol 35, 2010

[5] Volkskrankheit Rückenschmerzen: Eine Krankheit in Zahlen https://bomedus.com/blog/blogartikel/112_volkskrankheit-rueckenschmerzen-eine-krankheit-in-zahlen/)

loosening in this particular segment of interbody fusion surgeries.

spineFuse implants solve these problems, which have a significant impact on health insurance companies as well as on the patient's Quality of Life, pain perception and psychological well-being. The health insurance companies estimate the additional cost resulting of reoperations at more than EUR 1,000,000 per year in Germany alone.[6]

With the use of these implants, as discussed in this case study, the reoperation rate could decrease by more than 10% to a lower, single-digit value.

Potential savings in post-operative therapy costs

In addition to the relevant health-economic calculations, the use of functionalized implants also has potential savings per surgery performed, as post-op care can be significantly reduced (potential savings of EUR 2,500.00 per intervention performed and per post-op follow-up/re-visitation).

The health economic benefits/year could be estimated at EUR 381,687,500 [7] : [Interbody fusions/year in Germany (152,675)] * [Post-op savings potential (EUR 2,500)].

Potential savings for rehabilitation measures

Rehabilitation costs in Germany related to low back pain average 75 EUR / rehab per session. On average, 20 rehab sessions are prescribed within 24 months. The use of implants described in this case study can save up to 10 reimbursable rehab sessions as the patient is considered healed in year 2. spineFuse implants can save an additional 750 EUR/patient in 24 months.

The potential health economic benefit/year (Germany) could thus be calculated as 114,506,250 EUR [8].

Potential savings in post-op infection rates

The described stealth technology can help to reduce post-op infection rates. The number of cases in which spineFuse implants could be used at the beginning (fusion surgery) can be assumed to be about 10% of all spine surgeries performed per year: The total number of fusion surgeries performed annually in Germany amounted to a total of 111,259 cases [9].

With a 10% infection rate, reoperations due to infection affect 11,125 cases. The cost of lumbar fusion surgery is averaged at 13,500 EUR. Potential, health economic benefit/year (Germany): Calculated 150,187,500 EUR [10].

Potential savings in back-to-work time

To analyze the back-to-work ratio, and further assess calculations of the health economic benefits, the authors had to evaluate that the use of spineFuse implants could save 2 of the 8 post-op follow-up visits (12- and 24-month post-op visits), when the patient is considered healed after 12 months.

The cost of sick leaves/day due to low back pain is set at 108.38 EUR/day. In a theoretical three-rate calculation, the use of the implants described can reduce sick leave days by 25%. The saving of 23 sick days would mean an additional saving of 2,492 EUR per intervention. The theoretically possible, health economic benefit/year (Germany): 380,466,100 EUR[11].

[6] MedDEV News 06/2015
[7] Volkskrankheit Rückenschmerzen: Eine Krankheit in Zahlen https://bomedus.com/blog/blogartikel/112_volkskrankheit-rueckenschmerzen-eine-krankheit-in-zahlen/)
[8] Ebd.
[9] IneK Statistik 2019
[10] Volkskrankheit Rückenschmerzen: Eine Krankheit in Zahlen https://bomedus.com/blog/blogartikel/112_volkskrankheit-rueckenschmerzen-eine-krankheit-in-zahlen/)
[11] Volkskrankheit Rückenschmerzen: Eine Krankheit in Zahlen https://bomedus.com/blog/blogartikel/112_volkskrankheit-rueckenschmerzen-eine-krankheit-in-zahlen/)

Discussion

This discussion/case study should be used to demonstrate that not only the direct performance indicators should be taken into account to evaluate a medical device.

Anno 2020, a detailed analysis of the indirect performance indicators often provides a more precise picture regarding both advantages and disadvantages of medical devices within a specific indication.

Currently it's fair to say that decision makers still mainly evaluate the direct performance indicators, unfortunately. Maybe because it's often time-consuming and laborious to research and analyze the health system background of the respective indications and to place them in the context of the more obvious, direct indicators and to finally evaluate them. The authors hope to at least offer more perspectives of how analysis and measurements should be perceived and looked at in the future.

Company Profiles

Medical Innovations Incubator GmbH (MII) belongs by 100% to the non-profit foundation for medical innovations, Tübingen.
The MII realizes foundation's purpose – the promotion of medical innovations – by supporting young and innovative companies with know-how, methods and networking in the healthcare sector.

stimOS GmbH develops innovative technologies and procedures to refine, functionalize and activate implant materials. As a supplier and service provider, stimOS makes this technology available to implant manufacturers. stimOS products for implant surface functionalization under the label MBT are available in three different categories. www.stimos.net.

surgeSupply GmbH assists medtech companies in successfully achieving and maintaining ISO 13485 certification. In addition, surgeSupply team members offer their know-how in, sales and distribution, reimbursement, design and development activities, compilation of dossiers and reports for the clinical evaluation of medical devices. The company also provides general advisory services according to ISO 14155 and publication support: Bringing in many years of experience, surgeSupply deals with the most important scientific publications.