Master Thesis

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Constructive Technology Assessment (CTA) to assess the potential value of new technologies: The allocation and application to Sagittal Balance and spino-pelvic parameters in the clinical pathway of degenerative spine diseases.

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CTA to assess the potential value of new technologies.

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Abstract

Objectives: Constructive Technology Assessment (CTA) is proven to be a valuable concept for medical technologies that are still under development. This study applies CTA to assess the potential value of an innovative measurement concept in spine surgery, Sagittal Balance (SB). Prior research suggests improved clinical outcomes resulting from the SB application; however, it is not widely used due to various, still unidentified reasons. In this case, CTA was particularly utilized to identify these reasons and therewith SB's most efficient pathway allocation.

Methods: Data were collected using semi-structured interviews among European surgical spine experts with different experience-levels regarding SB. The interviews were structured according to the CTA domains: clinical, economic, patient-related and organizational. Subsequently, feedback from the interviewees was clustered according to specific clinical pathway stages.

Results: Nine semi-structured interviews were conducted. All CTA domains bared implementation barriers hampering adequate technology application (e.g. imaging and calculation difficulties), result interpretation (e.g. recognising different spine morphologies) and subsequent surgical interventions (e.g. comprehensive surgeries). CTA further assists to seek optimal allocation of SB in the clinical pathway by identifying implementation barriers in the diagnosis, treatment, post-treatment and follow-up stage.

Conclusion: SB was found to be a valuable concept by interviewees as diagnostic tool and outcome measure in the investigated clinical environments although its feasibility for the post-treatment and follow-up phase was limited and warrants further research. CTA has shown to be a useful framework to assess the potential value of innovative technologies and additionally can contribute to its ideal allocation among clinical pathway stages.

Keywords: Constructive Technology Assessment, Spine, Biomedical Technology IS, Sagittal Balance

Introduction

Nowadays health policy makers are under pressure to make decisions regarding reimbursement in an earlier stage than they are traditionally accustomed (14). Dynamic technologies still under development are characterized by limited data availability resulting from slow adoption, which prevents classical Randomized Controlled Trials (RCTs). RCTs generate valid data for Health Technology Assessment (HTA), typically Cost-Effectiveness Analysis (CEA), constituting a frequently used evaluation approach to enable decisions on coverage and reimbursement of new or existing technologies (26). Besides the remote applicability of CEA for developing technologies, Ijzerman et al. further identified a considerable mismatch between information needs of several decision makers and CEA results (15). Explanatory insights derived from qualitative investigations (e.g. stakeholder interviews) in an early development stage can generate more real-world results that counteract the mismatch concerned and thereby facilitate decision-making. Insights particularly highlight barriers to diffusion and allow for the anticipation of evidence required for later CEA. This enables the subsequent influence of the technology's implementation and its optimal allocation for entire clinical pathways and ultimately improve the technology's diffusion (11; 13). Constructive Technology Assessment (CTA) presents a thorough methodological framework for early technology assessment. By emphazising sociodynamic processes it has the potential to improve the technology design and implementation rather than merely assessing its impact through early HTA that does not allow for technology dynamics (7). Sagittal Balance (SB) is an example of a promising concept that potentially improves the diagnosis of (degenerative) spine diseases and the outcomes of interventions (1). In spite of the variability of Chronic Low Back Pain (CLBP) and the lack of standardization in measurement and reporting, the socioeconomic impact of degenerative spine diseases is systematically considered high and growing. It has a detrimental impact on patients' Quality of Life (QoL) and functioning with the physical component being the most affected dimension. Health-related Quality of Life (HRQoL) is lower than in serious chronic illnesses (e.g. cancer, heart failure, COPD, depression) (10). A recent systematic review by Dagenais et al. has summarized the results of studies reporting the financial impact of CLBP in the US and internationally. When transformed in US dollars, the total costs range from USD 1.5 to USD 18.7 billion and mean direct costs accounted for only 22% of total

costs, indicating that indirect costs are a much larger contributor to the costs of CLBP. Interestingly, the largest mean cost components for care of CLBP were physical therapy (17%) and inpatient services (17%), followed by pharmacy (13%) and primary care (13%), outpatient services (8%) and diagnostic imaging (7%), with surgery contributing only with 5% (5). Considering the socio-economic relevance related to degenerative spine diseases, SB and spino-pelvic parameters are one of the promising paths of research to decrease the burden of disease and thereby costs.

SB refers to the positive correlation between thoracic kyphosis and lumbar lordosis that allows equal distribution of forces across the spine. Its disruption by disease or age results in deformity that translates in adaptive changes of the pelvis and lower limbs. These contribute in turn to further progression of deformity. Sagittal malalignment presents as an exaggeration or deficiency of normal lordosis or kyphosis. There is usually pain and functional disability along with concerns about self- image and social interaction due to inability to maintain a horizontal gaze (25). Its measurement has evolved from the one-dimensional description proposed by Scoliosis Research Society (SRS) - a plumb line drawn from the centre of the body of C7 that lies within ±2 cm of the sacral promontory – to the more comprehensive three-dimensional spino-pelvic parameters defined by Duval- Beaupère and Legaye (18). Roussouly et al have subsequently used this approach in 160 normal adults to validate the interdependent relationship between lumbar lordosis and pelvis and identified 4 main patterns of sagittal alignment (24). Anecdotal evidence suggests patients with symptomatic disc disease are most commonly classified as Type 1 (short lumbar lordosis and significant kyphosis in upper spine) or 2 (hypolordotic and hypokyphotic spine), while spinal stenosis is usually associated with Type 4 (hyperlordotic spine) and type 3 is rarely seen in patients with spinal disorders. Chaléat-Valayer et al. have recently confirmed the strong interdependence between the pelvis and the lumbar spine to maintain a balanced posture and observed its contribution to the development of CLBP in a case-control study of 198 patients and 709 normal subjects using the same spino-pelvic measurements (4). Sagittal malalignement is thus considered critical in spine surgery planning and it has been suggested to contribute to failure of spine surgery and reoperations (15; 16; 20). Its application requires the performance of radiographic measures including full-standing x-rays and MRIs and demands specific archiving systems (2).

Considering the significant burden of CLBP and the observed influence of spino-pelvic parameters in spine-related morbidity, Technology Assessment (TA) of new diagnostic or surgical instruments for spine disease demands a better understanding of the consequences of postural variations in health outcomes and specifically in HrQoL (10). The spine medical community seeks firstly to understand whether the physical posture implies and causes certain pathologies of the spine, in particular degenerative diseases; secondly whether such pathology can be prevented or treated by adapting the sagittal alignment and the spinal-pelvic relationship (2).

Despite the promising value of SB and spino-pelvic parameters to inform surgery the extent of its application in spine degenerative cases, however, remains low. Identifying reasons for this limited diffusion from a TA perspective, with specific focus on spino-pelvic parameters, is subject to the present study. The recognition of different spine morphologies initiated an approach towards tailor-made solutions in degenerative spine surgery with a promising impact on patients' restored balance (3; 19).

Acknowledging the comprehensiveness of the SB concept, its spino-pelvic parameters and its capacity to enhance clinical outcomes by improving diagnosis, treatment and monitoring induces its designation as medical technology rather than merely as measures in this study. The marginal level of dissemination of this innovative approach and the technology's potential for amelioration and improvement, thereby, account for SB's early stage of development.

Currently the quantification of the actual value of the spino-pelvic parameters and its influence in surgical practice is challenging due to paucity of uniform data collection and co-existence of other technologies throughout the various pathway stages. Therefore, in this study we chose to apply Constructive Technology Assessment (CTA) as mean to assess implementation barriers resulting from SB and spino-pelvic parameters' dynamics and thereby detect the concept's potential value in the different stages of the clinical pathway of degenerative spine diseases (7; 11). To increase relevance of results, Lumbar Spinal Stenosis (LSS) has been selected as example for degenerative spine diseases. CTA is a useful framework to assess medical technologies in an early development stage like SB and the spino-pelvic parameters since it embeds in its process the iterative nature of technology development (22). Previous publications on CTA have proven the concept's value for design improvement of technologies in an early development stage (7). Only few publications highlight the practical use of the concept while little attention has been drawn to the role of

technologies in clinical pathways. Accordingly, CTA was here applied to analyze the potential value of SB and to detect implementation barriers in the current application practices that can subsequently be eliminated to improve the technology's effectiveness (7) and inform allocation of research and development efforts.

Methods

Design

The design of the study is according to the method of Constructive Technology Assessment (CTA), where the various aspects of SB and spino-pelvic parameters were investigated according to the four domains of CTA: clinical, economic, patient-related and organizational (7). Lacking standardization and rare documentation and monitoring activities regarding SB affected the need for exploratory qualitative data collection by means of semi-structured in-depth interviews subsequent to the literature research (21).

Clinical case

In order to assess the potential additional value of SB for degenerative spine surgery, current surgical management of a specific degenerative spine disease, Lumbar Spinal Stenosis (LSS), has been investigated in terms of the "common" clinical pathway (see Fig. 1). LSS represents the most common indication for lumbar spine surgery. With the use of precise clinical activities in each pathway stage a certain baseline could be identified while results became more tangible. Recent clinical values obtained by surgical specialists who adopted SB were subsequently compared to clinical values maintained before the adoption of the technology. Through this comparison the actual impact of SB on the surgical management of LSS (see Fig. 2) as well as decisive points for an effective adoption of the technology were highlighted and examined in the light of the four CTA domains (see Fig. 3).

CTA domains

For the clinical domain, the interviewees were questioned regarding the effectiveness of SB, in terms of SB as a diagnostic tool and outcome measure. Economic aspects interrogated in the interviews refer to budgetary constraints hampering the implementation of SB. Moreover, patient related aspects were questioned by asking the experts for their estimation of patients' potential benefits when applying SB as standard care. Lastly, organizational aspects were investigated by questions regarding institutional requirements and limitations impacting the implementation process.

Characteristics of the interviewees

Non-randomly selected spine surgical experts across European health care systems were approached to participate in the interviews. This guaranteed an equal representation of both specialties, neurosurgeons and orthopaedic surgeons, and international coverage. Moreover, different experience levels were included as well as different levels of readiness or willingness to apply the technology concerned. For this purpose, Rogers' diffusion curve was used that phases subjects from innovators, over early majority and late majority, towards laggards (23). The interviewee segmentation is essential to ensure an adequate interpretation of the qualitative data set obtained through the interviews (21).

Procedure

All specialists received a briefing document *ex ante* that aimed to align argumentation components without anticipating any interpretation. It comprised amongst others the illustration of the clinical pathway of LSS to provide contextual guidance throughout the interview (see Figure 1). The interviews constitute one feedback tool as suggested by the CTA methodological framework (7): Feedback generated through such interviews should be fed back in the development process of the technology to improve its design and thereby the effectiveness of its application. This approach accentuated the dynamics and essential aspects of SB to be evaluated and required flexible design adjustment throughout the interview progression regarding the questions posed (21). A textual data format obtained from audiotapes and interview notes was used in combination with scientific data gained through the anteceded literature review.

Data analysis

Interview questions and answers were organized according to the four relevant clinical pathway phases (diagnosis, treatment, post-treatment and follow-up) to guarantee the consideration of the entire surgical management of LSS as example for degenerative spine diseases when analyzing the potential value of SB. Information obtained in the course of the interviews was decoded congruent with the four CTA domains. The data was processed in Excel Microsoft 2007.

Results

Interview results are presented in four sections corresponding with the four CTA domains.

Interviews

Response rates were in general 60%, 57% among the SB enthusiasts, while 100% among the SB critics. A large fraction of interview subjects belonged to the early majority (n=6) whereas only a minor interviewee fraction belonged to the innovators (n=2) and laggards (n=1). No interview subject was categorized as belonging to the early majority or late majority (23).

Clinical aspects

7/9 interview subjects confirmed an improved diagnostic work-up after the application of SB and spino-pelvic parameters as patients' imbalance and pain source can be accurately detected. Regarding the treatment choice, 5/9 spine experts interviewed claim for interpretation guidance of the measurement results in order to secure appropriate surgical interventions and potential tailored solutions. However, 3/9 interviewees remark a sceptic attitude towards tailored surgical solutions. SB restoration was expected by 6 experts to lead to fewer revision surgeries highly impacting clinical outcomes (80%), mainly HrQoL (80%) (see Fig. 3).

Economic aspects

8/9 interview subjects declare cost-containment resulting from a reduction of revision surgeries and consequently better long-term outcomes. The introduction of SB is further considered economically beneficial by 3/9 interviewees due to the fact that clearer diagnosis offsets investments in recurrent radiological examinations. However, 6/9 experts reported concerns about inevitable additional costs due to time-consuming measuring, examination, monitoring and education related activities when applying SB. Speculations were enunciated by 1/9 specialists regarding potential additional expenditures originating from accelerated utilization of instrumentation in surgery and rising complications from more extensive surgical interventions (see Fig. 3).

Patient-related aspects

8/9 interview subjects declared that the application of SB and spino-pelvic parameters generally accelerates the detection of patients' pain sources and, therefore, facilitates the surgical decision. 3/9 interviewees agreed that patients are most significantly affected by the regained sagittal balance after a successful alignment of the spine. Through the consideration of the Pelvic Incidence (PI) in addition to the C7 Plumb line (C7 PL), 6/9 specialists recognize an increased amount of balanced patients and therefore increased pain reduction for patients. 5/9 experts indicate to achieve differential diagnosis in more than 90% of LSS cases through the application of SB.

7/9 interviewees consider patients' improved HrQoL being primarily associated with respective pain relief after SB has been restored while 4 interview subjects estimated an increase in HrQoL of 50% and higher after SB application. In the short-term patients may be negatively affected by potentially increasing complications and recovery times as 3 experts apprehend (see Fig. 3).

Organizational aspects

2/9 experts highlighted that young surgeons would show a higher preparedness for implementation than their senior colleagues. Contrariwise, senior adopters and so-called innovators as termed by Rogers' adoption curve were considered immensely fundamental by 6/9 experts for the training of younger surgeons and the acceleration of the diffusion process (22). 8/9 interviewees further confirmed the high impact of SB application on the choice of the surgical technique. Consequently, 2/9 experts had to train the performance of additional surgical techniques in the course of the SB implementation.

Overall, 7/9 experts perceived extensive education of the concept to the staff as most important aspect to overcome implementation obstacles while 3/9 considered changes in IT supply (PACs) and 1/9 changes in radiographic instruments supply as most crucial factor. In contrast 2/9 reported organizational conditions as sufficient for successfully implementing SB. 8/9 experts assessed spinopelvic parameters in the diagnostic phase of the LSS pathway while 6/9 deployed it in the post-treatment phase (<6 months). The amount of interview subjects who reported to accomplish the measures in the follow-up phase (>6 months) totalled 3/9 (see Fig. 3).

Discussion

Our results showed that the majority of physicians in the field of spine surgery think that SB and spino-pelvic parameters is a strong concept and measurement that may enhance the surgical management of degenerative spine diseases in case of adequate application and interpretation. SB entails likewise other medical technologies a steep learning curve, which is a "controlled" barrier of adoption (4).

From the interviews, it became apparent that despite the accurateness of the measures concerned (manually or software-based) and their eminent prognostic value it remains ambiguous which surgical technique to chose once parameter values have been obtained (25). Interpretation guidelines as researched by Roussouly et al. could eliminate this uncertainness (25); however, some surgeons fear a deficit of professional autonomy as a consequence of guideline implementation. Others expressed concern about the potential rise in invasiveness of surgeries such as pedicle subtraction osteotomy implying potential extensive recovery times and increased co-morbidities (6). Customization will, nevertheless, persist to a certain extent due to the recognition of variability in the spino-pelvic profiles and other contributable variables in surgical outcomes, suggesting individual surgical solutions (19). Tailored surgical solutions that consider standardized parameters may generate a reduction of revision surgeries thus positively impacting short-term as well as long-term outcomes (3). Concerns were raised with regards to increased expenditure of time when measuring spinopelvic parameters, initiating tailored solutions and monitoring outcomes, which constitutes additional costs for health care systems. This economic burden may be outweighed by patients' benefits indicated by HrQoL as consequence of applying spino-pelvic parameters resulting in patients' improved balance (10). Obstacles particularly occur in the post-treatment and follow-up stages mainly as a consequence of unfeasible organizational structures such as lack of personnel, time and adequate outcome measures. Moreover, healthcare systems, typically public systems, where patients are often merely entitled to one post-operative check-up anticipate a consequent monitoring of long-term results (9). Establishing SB and spino-pelvic parameters as outcome measure in these countries would entail supportive actions by administrative authorities.

Barriers in the diagnostic and treatment stage are research as well as expert driven whereas barriers in the post-treatment and follow-up stage are primarily caused by institutional limitations and economic constraints. The potential to overcome obstacles in the former stages is expected to be higher than to abolish those in the latter stages where required adjustments are more complex. Accordingly, the implementation of SB and spino-pelvic parameters is suggested to be more feasible for the diagnostic and treatment phase than to post-treatment and follow-up.
The moderate diffusion level linked to SB hampers a desirable large-scale interrogation of experts and determines the present sample size (21). Despite the limited interrogation scale, obtaining explanatory insights in the technology's implementation process at this stage of diffusion, as achieved by the CTA methodological framework, is beneficial and therefore advisable (22).
Qualitative findings should at first serve as prior basis for decision-making and later as additional input for HTA allowing for more profound decision-making (14). As technologies' diffusion process naturally involves primarily enthusiasts at the beginning, this study is limited regarding the extend of critical feedback (23). This limited availability of critics resulted in an enthusiasts-oriented contacting of experts, generating a selection bias (12). It is fundamental, therefore, to recognize the marginal representation of SB critics (only 1 expert) in the study sample by assigning significant value to their concerns. Without the cautious consideration of the selection bias in the analysis of the study results concerned, the result interpretation is likely to be in favour of SB enthusiasts overemphasizing their statements (12).
Future research should continue to elaborate on critics' concerns to improve the technology's design. Further research and development should focus in automatizing and standardizing spino-pelvic parameters measurement and subsequent proof of concept (11; 25). This requires validation of the subsequent surgical corrections and its relationship with relevant self-reported and performance- measures, as well as, cost offsets from increased physical functioning and decreased complications and revision surgeries (10, 16). Interviews are limited to a high-expert group of surgeons in this study which could be extended to other relevant subgroups in the future such as other staff (e.g. nurses or less experienced surgeons), payers and policy-makers in the various countries (22).
Strengths of our study were the thorough identification of implementation barriers and facilitators by a multifaceted, realistic sample that generated a broad data record (21). Applying

the CTA framework showed to be a solid approach when gathering information on a dynamic medical technology (7). This study is intended as qualitative and exploratory basis for subsequent quantitative research approaches on SB and spino-pelvic parameters as it highlights decisive aspects that should become subject to future investigations.

The driving barriers of the decelerated adoption and implementation of SB in clinical practice appeared to be the lack of clarity regarding surgical procedures required and potential negative patient outcomes as a consequence of applying SB (6).

Finally, the most feasible allocation of SB in the clinical environments assessed appeared to be in the diagnostic and treatment phase implying the great need to further assess adjustments needed to overcome the hampering conditions present in the other pathway stages. It should be noted though that without its concomitant implementation in post-procedure and follow-up stages and uniform collection of data on the same spino-pelvic parameters the assessment of its actual value is impaired.

SB and spino-pelvic parameters emerged as suitable standardization tool regarding the surgical management of degenerative spine diseases due to its positive impact on patients outcomes and therewith cost-containment initiatives (10; 17). Some degree of interpretation guidance, however, is essential to align surgeons' approaches and ultimately standardize clinical pathways of diseases concerned such as LSS. The dramatically increasing prevalence of degenerative (spine) diseases and therewith linked healthcare expenditures demand a sound consideration of SB in the future.

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Figures 1-3

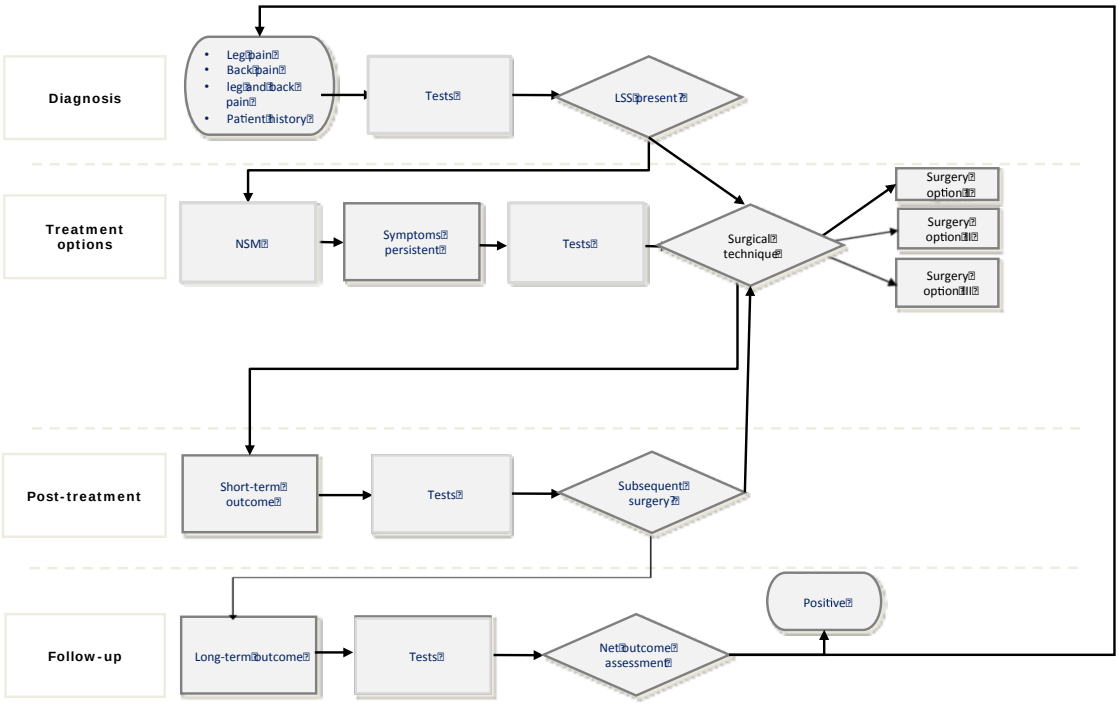

Figure 1. Clinical pathway of LSS.

* *NSM* = Non-surgical management; *LSS* = Lumbar Spinal Stenosis; *Tests* = diagnostic measures (e.g. physical examination, radiographic measures); *Net outcome assessment* = outcome measures

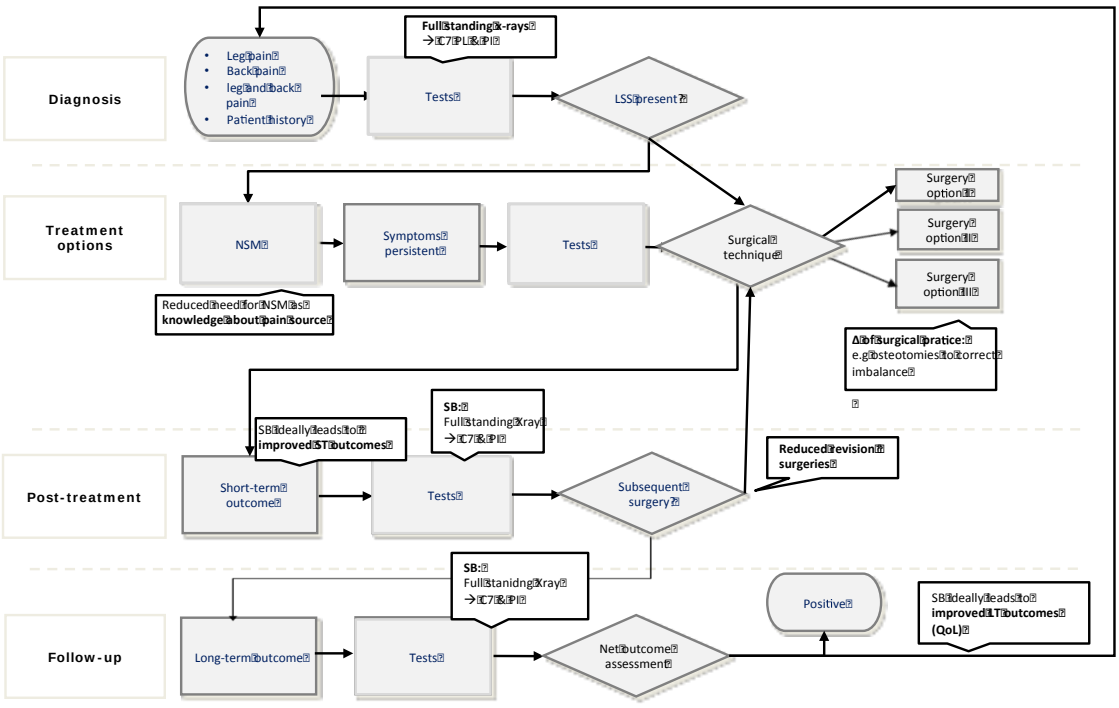

Figure 2. Potential allocation of SB and associated required actions (highlighted through legend remarks) in the LSS clinical pathway indicating its' additional value.

* *NSM* = Non-surgical management; *LSS* = Lumbar Spinal Stenosis; *Tests* = diagnostic measures (e.g. physical examination, radiographic measures); *Net outcome assessment* = outcome measures

	Diagnosis	Treatment	Post-treatment	Follow-up
Clinical	– Assessment of parameters established in this phase (90%,+) – Diagnostic work-up (80%,+) – Patients' symptoms must match radiogr. measures (30%,+/-) – Result interpretation(60%,-) – Differential diagnosis >90% (60%,+)	– Reduced need for NSM (80%,+) – Surgical expertise for tailored solutions (30%,-) – Impact choice of surgical technique (90%,+/-) – Increase in complicated surgeries (osteotomies) (10%,-)	– Costs of radiographic instruments (30%,+) – Time consuming measures (70%,-) – Assessment of parameters established in this phase (70%,+)	– Assessment of parameters established in this phase (30%,+/-) – Unclarity about QoL indicator (80%,-)
Economic	– Calculation of angles is time-consuming (70%,-) – Availability of PACs (90%,+/-)	– Training additional surgical techniques(20%,-) – Potential increase in instrumented procedures (payers' perspective) (10%,-)	– Cost-containment due to reduced revision surgeries (90%,+)	– Lack of clinical personnel for measuring and monitoring outcomes (60%,-)
Patient-related	– Detection pain source (90%,+)	– Potential extensive surgeries + recovery (10%,-)	– Greater reduction of pain due to restored balance (70%,+) – Extensive recovery and potential complications (30%,-)	– HrQoL most desirable outcome (80%,+/-) – Improvement of HrQoL >50% (40%,+) – Time consuming monitoring and evaluation (70%,-) – Sagittal alignment highest impact on outcomes (30%,+/-) – Psychological and physiological discomfort (30%,-)
Organisational	– Young surgeons higher preparedness to implement (20%,+) – Implementation takes >4 months (70%,-) – Sufficient techn. infrastructure (30%,+) – Presence of experienced staff (70%,+/-)	– Presence of experienced staff (70%,+/-) – Extensive education (80%,-) – Readiness for individ. surgical solutions (30%,-)		– Suitability of outcome measures (60%,-) – Radiation dose per patient (10%,-)

Figure 3. Barriers (+) and facilitators (-) identified throughout the implementation process of SB. The % value further indicates the amount of interviewees who mentioned the aspect concerned.