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1ST INTERNATIONAL SPINE EXPERT SYMPOSIUM

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COLLECTION OF ABSTRACTS

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STATE-OF-THE-ART IN DEGENERATIVE SPINE SURGERY

INTRODUCTION

Lumbar fusion surgery has been performed since a long time with good outcome for treated patients. In the 80´s and 90´s we could talk about an era of treatment philosophy. Later there has been a tremendous development in the instrumentation and the components we are using in our daily practise, and many of the tools developed have helped to facilitate the surgical procedure; we could say "the era of product development". But did we always understand the consequences occurring by using all these devices? The aim of this presentation will be to present a status update on where we come from, where we are, and where do we go to in today spine fusion surgery.

THE ERA OF DISCOVERY AND UNDERSTANDING

The evolution of spinal surgery started more than two hundred years ago, and the first instrumented cervical spinal fusion was performed by Hadra in 1891. During the first half of the twentieth century the surgical techniques developed and new products and materials were introduced. From the 40's onwards new fusion concepts were implemented including instrumentation and grafting to achieve fusion.

THE ERA OF TREATMENT PHILOSOPHY

During the second half of last century techniques and concepts were further developed. The profession showed interest in things like spine biomechanics, approaches (TLIF was described), how pedicle screws should be placed, etc. The goals for spine fusion surgery were established and accepted in the spine community: To restore stability and balance, achieve optimal clinical results, and avoid complications.

THE ERA OF PRODUCT DEVELOPMENT

An incredible development of new products have occured in the last twenty-thirty years. Different type of screws, peek for PLIF, TLIF, ALIF, porous titanium, nanotexture surface, navigation assisted surgery, robotics ...

Where does this position us? Where are we? Did all these products help us to increase fusion rates, improve clinical outcomes, and lower the rates of complications?

By reviewing the literature, it is obvious that when looking at booth different techniques described and materials used in clinical studies on spinal fusion, the conclusion is very often that similar fusion rates and clinical outcomes are seen. So what is missing?

CONCLUSIONS

Is it time now, to re-enter to a new era of treatment philosophy?
To focus again on what we are doing, how we are doing it, and how it will influence the final clinical outcomes for our patients. To consider better the biology of the patient, and the biomechanics of the spine. To restore the natural balance of the spine, preserve mobility, and do as less harm as possible to muscles and the neural tissues.

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HOW SURGICAL STRATEGY MAY IMPACT ASD

INTRODUCTION

Fusion and clinical success rates have increased because of improvements in techniques and instrumentation. In contrast, complications of fusion surgery are reported. The development of adjacent segment degeneration, or adjacent segment disease (ASD), is considered to be one of the most important potential long-term complications of spinal fusion leading to deterioration of the surgical outcome and often requiring further surgical treatment.

EVOLUTION OF SPINE INSTRUMENTATION

We are able to reduce severe spine deformations while reducing surgical morbidity, for both trauma fractures, scoliosis and isthmic spondylolisthesis. We believed we were at least as efficient in degenerative spine diseases: This was right – but only in short time! We gradually saw degradation of the initial results of our spinal fusions: ASD, ASP, PJF, PJK. Is this a result of the natural history of the degenerative aging spine? Or is our surgical technique one cause of ASD occurrence?

DEGRADATION OF THE INITIAL RESULTS OF SPINAL FUSION

Maruenda et al. published recently 15-years follow results of lumbar fusion surgery showing 50% radiographic ASD. Other publications present radiological ASD rates in the same range. In the same publication, the rate of recurrent surgery was 37.5% because of ASD. Other papers report around 25% recurrent surgery due to ASD. Degenerative disease is a totally different/architectural disease, and will continue year after year. To minimize the incidence of ASD, we need to re-analyse the degenerative spine disease, and its surgery, which both are much more complex than what we initially thought.

HOW TO MINIMIZE THE ASD INCIDENCE

In the literature a number of risk factors are discussed for contributing to ASD, with the current evidence reporting on factors including both the natural history of the patient, patient/disease specific factors, and factors depending on the surgical approach. Today we are able to improve our practice, we can choose our surgical strategies among many available techniques, but we must adapt our surgical technique to the patient. Decompression technique and Instrumentation (facet violation, stress concentrations/stiffness, number of fused levels, and sagittal malalignment) are factors discussed in the literature to have an impact on the development of ASD. Numerous publications conclude that fixation systems that produce stress concentration at the adjacent segments create the greatest amount of adverse effects to the intervertebral discs. We should minimize the amount of constraint built in to our constructions.

CONCLUSIONS

- The degenerative spine disease is a much more complex problem than previously thought
- ASD incidence is a real problem: it has an impact to our practices
- Reduce ASD incidence by a better patient selection, and improvement of surgical strategy and techniques.
- The ideal surgery should consider: Adapted surgical approach/case – anterior, posterior, or both;
  No systematic decompression; Efforts to obtain best alignment with the least efforts/forces;
  Gentle device implantation; Min. number of fused levels; Instrumentation as non-constraint as possible
- In degenerative disease, fusion is an alignment surgery. Stabilization fusion with the best balance

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THE NON-CONSTRAINT TECHNIQUE FOR ENHANCED FUSION AND OUTCOMES

INTRODUCTION

Spinal fusion surgery is one of the most common treatments spine surgeons currently perform. However, the surgical techniques used can widely differ depending on the training and the experience surgeons have.
Many surgeons have relied on the evolution of technology to achieve better outcomes for patients while forgetting about the power of what a foundational surgical philosophy and technique can provide to facilitate better outcomes.
With the non-constraint surgical technique, it is potentially possible to improve fusion, and limiting both short- and long-term complications. The aim of this presentation was to give a first introduction to where we are standing today, and to introduce the non-constraint philosophy.

COMMON COMPLICATIONS

Based on results published in the literature we recognize four main complications seen in spine fusion surgery: Screw Malposition, Pseudo-arthrosis, Sagittal Misalignment, and Adjacent Segment Disease (ASD). These complications can in different ways contribute to poor outcomes.

NON-CONSTRAINT PRINCIPLES

By the term non-constraint we understand to reposition the spine in a neutral alignment, and hold the construct in this renew position with minimal forces on the screws and rods. In the degenerative spine, the vertebral bodies and ligaments are more and more fixed in a misalignment.

To lower the rate of the common complications described above, the fusion should be accomplished in a realigned spine, in the sagittal, axial and as well the coronal plane. This realignment should be obtained by proper release of pathologic bone and ligaments instead of using powerful instruments such as persuaders. The traditional surgical approach of using powerful instruments to force the implants, and secondarily the vertebral bodies, into place put excessive and unnecessary loads on the spine and should be avoided. Instead, the surgically achieved mobility and flexibility of the released spine should be used to evenly distribute the biomechanical forces across the anatomy and the construct.

SURGICAL TECHNIQUE - STEPS FOR IDEAL FIXATION

- Extensive release – for proper vertebral mobilization
- Accurate screw trajectory and placement – to increase anchorage
- No over-screwing – to preserve the implants polyaxiality
- Non-constrained rod placement – to minimize pull-put forces on the screws
- Symmetrical rod tightening – to minimize torsional stresses

These steps allow you to maximize your construct integrity while minimizing the implant forces applied during the procedure. Improving outcomes through technique!

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3D APPROACH TO SPINAL ALIGNMENT: IS THERE SOMETHING BEYOND THE SAGITTAL PLANE?

INTRODUCTION

For many years the "Sagittal balance" has been one of the most discussed topics in international spine congresses and meetings. Numerous papers have been published on the importance of a correct sagittal alignment, while less attention has been given to coronal imbalance and rotations, global balance.

WHAT WE KNOW

The coronal alignment of the human spine is well understood. It is normal when straight, and pathologic when curved (scoliosis). Sagittal alignment of the human spine and pelvis in a standardized standing position is highly variable in different individuals. It has been shown that sagittal imbalance has a higher impact than coronal imbalance in Health Related Quality of Life (HRQoL) and surgical outcomes. The aging spine tends to lose the characteristic shape of the spine (less lumbar lordosis, and more kyphotic thoracic spine), AND this has a high impact in HRQoL. This will be compensated by a tilting of the pelvis, and when that is not enough, knee flexion. These mechanisms maintain the line of gravity but is not ergonomic. It leads to contractions in posterior spine muscles, and low back pain. Young patients have good muscle capacity, and will compensate easier than elderly. The compensation increases the forces on the discs.

At least three sagittal alignment values are correlated with outcomes in terms of pain, function, and HRQoL: Sagittal Vertical Axis translation (SVA): < 5 cm; Pelvic Tilt (PT) = 0.37 PI – 7° (PT < ⅓ PI); Pelvic Incidence-Lumbar Lordosis (PI-LL) mismatch: PI-LL < 10°.

WHAT WE THINK TO KNOW

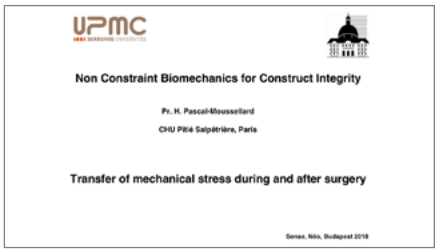
We are able to restore the balance …
Leveque JCA, et al. (2018) showed that preoperatively, 173 (30 %) patients exhibited malalignment. Postoperatively, 161 (28 %) of patients were mal-aligned. Alignment was preserved in 63 %, restored in 9 %, not corrected in 21 %, and worsened in 7 % of patients.

Rothenfluh DA, et al. (2015) demonstrated that, at an average of 4 years after a primary one-, two-, or three-level lumbar fusion, 26 % of patients with a pelvic incidence-lumbar lordosis mismatch < 10° underwent revision for ASD, while 78 % of patients with a PI-LL mismatch ≥ 10° did.

WHAT WE WOULD LIKE TO KNOW

- How much restoration does the spine need?
- How can we restore the spinal balance?
- How can we minimize the revision rate?
- Is there anything better than the fusion?
- Why do new devices in spine surgery seem so promising at first, and disappear so quietly?

These questions are still open for discussion.



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NON-CONSTRAINT BIOMECHANICS FOR CONSTRUCT INTEGRITY

INTRODUCTION

Pedicle screw systems attempt to restore the normal biomechanics of the spinal column by restoring the alignment of the spine, the unloading of the intervertebral disc, and the posterior elements.
Much focus has been given on how to facilitate the surgical procedure for surgeons, with the development of new instruments and tools, without really considering how it will affect the final outcomes.

WHICH ARE THE PROBLEMS?

Transfer of constraints into constructions used in fusion spine surgery has been confirmed in biomechanical studies. Stress and strain in constructions will have an impact on clinical outcomes.

Per-operatively: Immediate transfer of mechanical stress
Poor anchorage: Poor correction;
Loss of anchorage: Pull-out

Post-operatively: Late and continuous transfer of mechanical stress
Inside the construct: Loosening, Rod breakage;
Extremities of the construct: PJK, DJK

The effects of late and continuous constraint and stress to constructs and surrounding tissues is not fully understood. Rate of screw loosening shown in the literature: 1–60 %.

CLINICAL STUDY

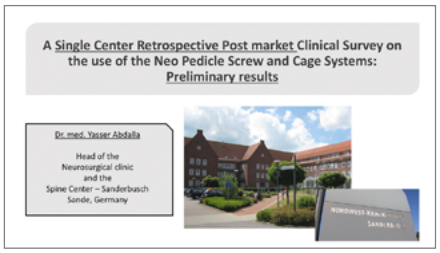
"Marie-Hardy L, Scemama C, Pascal-Moussellard H. Loosening and pull out of pedicle screws in spine surgeries: Prevalence and risk factors".

Retrospective, monocentric study to evaluate 1. Screw pull out (failure) 2. Clear zone (osteolysis) > 1 mm around implant 3. Identify risk factors. 166 cases. FU > 6 months.
Results: Pull out: 9.6 %; Clear zone: 40.4 %.
Risk factors for failure: Sagittal imbalance, Osteoporosis, and CrCo constructions (stiff)
Risk factors for clear zone: Same as above, and additionally impact from the Number of instrumented implants, No anterior support, and Pelvic fixation
Variability of prevalence and risk factor in the literature is depending of the definition. Better knowledge of the risk factors will help us to prevent failures.

CONCLUSIONS

Population is older and older, asking for good quality of life. Anchorage is often a problem due to the poor bone quality.
Different steps discussed to minimize the risk of failure:

- **Perioperatively:** Avoid using persuader (minimize constraint), Pre-bended or computer assisted bended rods, Connector for sharing the forces, Cement augmented screws.
- **In long term:** Good planning, well realized (sagittal balance), Add anterior support, Not using too rigid rods, Transitional vertebroplasty, Problem with pelvic anchorage.



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A CLINICAL PERSPECTIVE ON THE NON-CONSTRAINT TECHNIQUE

PURPOSE

Since 2016 Dr. Abdalla has been using the Neo Pedicle Screw System, adapting the non-constraint technique in the daily clinical practice in the neurosurgical and spine department. This is the first clinical survey of a significant number of patients treated, and with the objective to evaluate retrospectively the safety and performance of the Neo Pedicle Screw System. In addition, to evaluate the clinical experience in learning, understanding, and optimising this new surgical technique.

METHODS

A single centre post market retrospective clinical follow-up survey, including patients with pathologies that require stabilization, fusion of the thoracic and/or the lumbar spine (Degenerative disc disease, Spondylolisthesis, Pseudarthrosis, ASD, Trauma, infection, Tumour). 1 year follow up.
Inclusion of 106 patients treated from November 2016 until June 2018, male: 43; female: 63. Mean age: 70 (range: 18–89 years). Mean BMI (kg/m²): 28.9. Diagnoses: Degenerative diseases: 38, Trauma: 56, Infection: 8, Tumour: 4. Type of surgery: Open: 22; Mini-open: 32; PC: 52. Number of levels: 1:22; 2:19; 3–5:61; > 5:4.

RESULTS

Mean duration of post-operative follow-up: 11 months (at 3 months: 105; 6 months: 88; 1 year: 40). Time of surgery: mean: 75 min (median: 64 min). Blood loss: mean: 250 ml (range: 100–1250). Length of Hospital stay: mean: 10 days (range: 6–29). 75 % of patients had improved Low back pain score at their follow up visits. Reduction in pain (VAS): Pre-op (mean): 8.1; at longest FU (mean): 3.6. Functional disability (ODI): Pre-op (mean): 32; at longest FU (mean): 11. Radiological outcomes: At 6 months (88): no pseudarthrosis. Adverse events (AE): 29 (27 NSAE, 2 SAE). Rate of SSI: 1/106.

Clinical experience shows that for best result achieving reposition/reduction in spondylolisthesis:

- > ⅓ through proper release
- about ⅓ from the cage insertion
- < ⅓ over the pedicle screw-rod construction (no need for a reduction device)

CONCLUSIONS

- The first preliminary results indicate that the Neo system is safe and effective
- That the Neo system is suitable for most common pathologies of the thoracic and lumbar region needing fusion (T4–S1)
- Neo system is ideal to be used with a non-constraint surgical technique
- Changed approaches from open surgery to perform more mini-open surgeries
- Time saving procedure; both in preparation and in surgery

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SURGICAL SITE INFECTION – IMPACT & PREVENTION

INTRODUCTION

Surgical site infection following instrumented fixation of the spine is a feared complication. In particular, infections associated with an implant are difficult to treat since bacteria attach to the implant surface and form so-called biofilm colonies. Usually, revision surgery is required along with long antibiotic treatment that may put patients at high risk. SSI is complex and has not only a medical, but also an economic impact.

GENERAL NOTIONS

SSI appears within the first year after treatment. The reported SSI rates vary in the medical literature, from around 2% up to 12.7% reported for thoracolumbar spine fusion surgery (McClelland S, et al. 2016). The most common pathogen agents involved are intrinsic (staphylococcies). Anaerobic sepsis is the most difficult to treat. Revision surgery is needed in many cases. Risk factors reported in the literature are: diabetes, obesity, smoking, intraoperative complications like dural tear, or postoperative complications like transfusions.

CLINICAL IMPACT

SSI has an impact on the hospital length of stay and morbidity. Casper DS, et al. (2018) presented from their study evidence for increased mortality following elective sine surgery, and Petilon JM, et al (2012) showed that despite clinical improvement compared to the preoperative status, the SSI group of patients had a significantly worse back pain score than the control group two years after surgery.

ECONOMIC IMPACT

Several studies and publications focus on the economic impact of the SSI. Lissovoy G, et al. (2014) concludes that SSI is associated with a significant economic burden, analysing the cost per patient to around USD 20,000 per admission and extended the hospital stay by 9.7 days. Whitehouse JD, et al. (2002), observed that SSI prolonged the total hospital stays by 2 weeks, and increased the cost by more than 300%.

CAN WE REDUCE THE RATE OF SSI?

In a prospective clinical study comparing single-use instrumentation to reusable instrumentation, Litrico S, et al. (2016), the rate of SSI was 2% in the single-use group compared to 6% in the control group. Repeated reprocessing of implants has been discussed in numerous papers (McAuley T, Agarwal A) showing the negative effect of repeated sterilization cycles on surface contamination and corrosion. These studies are giving a new direction of thinking in the field, and are bringing interest in favour of the single-use systems.

TAKE HOME MESSAGES

- SSI may have an impact on the final clinical outcomes, and a global effect of the surgery
- SSI represents an important economic burden
- SSI is due to some unchangeable criteria, but we should try to improve factors that we can influence
- Single use instrumentation seems to decrease the rate of SSI. May be due to shorter duration of the surgery, minimal blood loss, reduced risk of contamination and corrosion from repetitive sterilization

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THE ECOLOGICAL FOOTPRINT IN SURGICAL INSTRUMENTATION

PURPOSE

Using disposable materials is proposed as safe systems that may reduce the environmental impact versus reusable materials, and in addition could provide a reduction of costs.
The higher contamination in the production of the disposable materials has often constituted the justification for the use of reusable material. The aim of this study was to assess the overall environmental impacts, comparing single-use surgical instruments of Neo Medical SA with conventional multi-use sets (e. g. Viper2).

METHODS

A comparative Life Cycle Assessment (LCA) for the application of single-use and multi-use surgical instruments for a one-level surgery was performed in the Technische Universität Braunschweig, Germany. All life cycle phases from raw material production over manufacturing and usage up to the end of life of the surgical instruments were considered.
An end-point indicator was used – ReCiPe Endpoint, 2008 – which aggregated 18 different impact categories contributing to human health, ecosystem quality, and resource availability. To investigate the robustness of the results and the influence of some assumptions (re-circulations and sterilization cycles), a sensitivity analysis was performed.

RESULTS

In global terms, the environmental impact is considerably lower for the single-use product. Its impact generates less cumulative energy demand and depletion of abiotic resources, has less impact on climate change, less potential acidification, and less particulate matter formation.
The aggregated single-score indicator (ReCiPe) depicts an overall benefit of 75 %. The main environmental impact of the single-use product is generated in the production phase. The major environmental impact results from the sterilization of the reusable set, mainly due to electricity use for the autoclave, and the water consumption for the washing.
The sensitivity analysis showed that an increase of number of surgeries per year has an insignificant effect on the entire environmental impact of the reusable material, but a bisection of sterilization cycles results in a serious reduction (loaner/consignment principle).

CONCLUSIONS

- This study shows that the disposable material (Neo Medical SA) used for lumbar fusion surgery has a lower environmental impact than the reusable material to which it was compared.
- The negative effect that occurs during the sterilization of the reusable material results in a better environmental profile of the disposable material.
- The disposable medical material can provide important advantages that have led to its gradual adoption in different fields of medicine.

Dr. Paul Licina
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THE PATIENT-CENTRIC SPINE PRACTICE – IS THIS THE WAY FORWARD?

SPINEPLUS

Patients consider spine surgeons to be experts for all back problems but their expertise lies in surgical treatment of specific pathology. Only 10 % of patients are surgical candidates. The group practice model is of little benefit to patients and can be daunting for a simple back problem.

Surgeons face the problem of having to see many patients who don't need surgery with loss of financial opportunity. They have little control over clinical prioritisation.

In response to these problems, a multidisciplinary patient centric practice was established, a relatively new concept for Australia. The team consists of a wide range of specialists and allied health professionals all with specific expertise in one aspect of back pain associated conditions. A triage system comprising a questionnaire and an algorithm is used to categorise patients according to clinical urgency. Other digital technologies and applications are used to streamline patient care. Multiple support staff and modern surroundings enhance the patient experience.

BACKSPACE

The multidisciplinary concept does not address all problems. Patients remain confused and frustrated by the myriad treatment options available. Without appropriate guidance they can "bounce" from one practitioner to another with the associated cost, inconvenience and lost opportunity. Clinicians have no control over referrals and limited input into post-operative care. There is no useful single digital solution that unifies all aspects of patient care.

In response, the "BackSpace" concept was established. It combines a modern holistic physical space and an innovated digital app and platform. This approach allows the clinician to modify the ecosystem, treating all aspects of back pain with a multidisciplinary clinic and accepting only patients that require surgery. After surgery, the patients return to BackSpace for optimal rehabilitation. The app facilitates communication and data collection, and gives patients control over their journey.

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THE AMBULATORY SURGICAL CENTER (ASC) MODEL IN SPINAL FUSION

Trends in the USA and potential global opportunities for value based care

AMBULATORY SPINE CENTER

Outpatient spine care has grown rapidly in the spine market, from 5,000 to 300,000 cases in the past 10 years. Today 50 % of the spine cases are outpatient and Medicare has added many outpatient codes. More instruments and implants available which are suitable for care in the ASC.

What – Same day surgery-patients are going home. No overnighters. No emergency care.
Why – Faster, Better, Cheaper. A way to stay in Private Practice. Today, there are 5,300 existing ASC's, and 70 new ASC's under construction in the US.
Flavors – MD Owner(s). Management Company. Hospital Partner. Big Health Corporation Owner.

Outpatient spine surgical procedures – how far can you go?

- MIS approach, Pain management, Image guidance
- Patient selection – ASA score I or II, General health, Setting expectations for the patient, Postoperative plan/coaching. 30 day readmission is 2.2 %. Complication rate 1.0 %
- Outcomes data – Length of stay, Pain and Function, Evidence based results
- Insurance payments – Fixed payment for a condition, Bundled payments, Implant costs
- Transparency in costs – Top tier medicine, Top value for services provided, Market driven health care, Alignment of the facility and the physicians

Outpatient spine care can provide great value, state-of-the-art medicine showing outstanding results for treated patients including less postoperative pain, and rapid recovery.

VALUE BASED MEDICINE

Intention to incentivize quality over quantity at a lower cost, by using evidence based medicine and patient centered care. For whom is the value?
We need to be able to measure costs correctly, and there is a need to develop process maps for the care cycle to be able to recognize the value of our treatments.
New payment models are taking over in the US, such as Medicare Payment Models, and BPCI = Bundled Payments for Care Improvement, replacing the "Fee for service". At this time, requested outcome measures are fairly simple, but are expected to be more demanding in the future. The value of data vs. the burden of data should be considered.

TRENDS IN SPINE FUSION SURGERY

- More complex procedures
- More MIS devices/instrumentation
- More robots
- More biologics/Stem Cells coming
- More burdensome data collection
- More Price/Performance pressure
- More disposable instruments

THANK YOU!

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