Value of 3D modeling in spine surgery

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PURPOSE OF THE STUDY AND BACKGROUND

Purpose of the Study

The aim of the study is to assess the clinical relevance of 3D stereographic reconstructions (from sterEOS 3D) on patients, adults and children, who undergo spine surgery. This study will observe the value of 3D parameters at three different steps of the standard of care surgical procedure: preoperatively, peri-operatively, and post-operatively. The goal of this prospective study is to observe how 3D reconstructions could enhance the planning, the surgery and the post-op analysis and outcomes. This pilot study could help to understand which and how 3D parameters could improve adult and pediatric spine surgery.

Background

EOS

The biplanar low-dose EOS system and its associated sterEOS workstation (EOS®, EOS Imaging, Paris, France) allows 3D spine reconstructions. The EOS system presents some advantages over MRI or CT Scans. The weight bearing position allows assessment in the functional position and the radiation exposure is 800-1000 times less then CT scans, allowing full spine acquisition even in pediatric patients. Selected anatomical landmarks are utilized to reconstruct a 3D model of the spine allowing global assessment as well as localized analysis.

Our hypothesis is that:

1. 3D parameters could bring additional information in pre-operative, surgery and post-op control.

STUDY DESIGN

The study will be prospective, randomized, occurring in New-York Presbyterian Hospital. The study design includes 4 arms:

- Cohort A: Adults and standard of care (EOS biplane acquisition). Planning performed with current practice.
- Cohort B: Adults and standard of care (EOS biplane acquisition). Planning performed with additional 3D information provided by 3D modeling on sterEOS software (FDA approved)
- Cohort C: Children and standard of care (EOS biplane acquisition). Planning performed with current practice.
- Cohort D: Children and standard of care (EOS biplane acquisition). Planning performed with additional 3D information provided by 3D modeling on sterEOS software (FDA approved)

For cohort B and D, 3D additional information will be provided to the surgeons. This information may help them to better understand the pathology and plan the procedure.

Radiographic, clinical parameters and freeform observations by the surgeon will be collected at pre-operative, peri-operative and post-operative steps, for patients who meet the inclusion criteria and signed the informed consent. The recorded parameters and freeform observations will be compared between patients of cohort A and B, and cohort C and D.

Number of Subjects

Every patient with spinal deformity meeting the inclusion criteria will be enrolled in this prospective pilot study. Around 160 subjects are anticipated to enroll in the project. Patients with spinal deformity will be identified during office hours of Dr. Lenke for adults and pediatrics, Dr. Ronald Lehman for Adults and pediatrics, and Dr. Michael Vitale, Dr B Roye and Dr D Roye for pediatrics. Patient will be segregated between the different cohort regarding their age (A and B for adults, C and D for children).

Age and Gender of Subjects

Both male and female patients will be included in the study. Regarding the age, the study will include every patient without age limit.

Racial and Ethnic Origin

For the enrollment of this study, there are no racial restrictions.

Estimated Duration of Study:

2 years (study end planned for July 2018)

Human Subject (Inclusion/Exclusion Criteria):

Adults:

Inclusion Criteria:

- All patients must be age 18 or greater at the time of surgery or initial consultation
- Having a primary surgery of their spine (Fusion or instrumentation)

Exclusion Criteria:

- Diagnosis of scoliosis other than degenerative or idiopathic (i.e. paralytic/neuromuscular, congenital)
- Undergoing revision (Fusion / Instrumentation)

EOS exclusion Criteria:

- Patients with supernumerary vertebrae (one extra or one less thoracic or lumbar vertebrae)
- Patients with hemivertebrae
- Insufficient quality of images to perform the 3D modeling with sterEOS software

Children:

Inclusion Criteria:

- All patients must be younger than 18 at the time of surgery
- Having a primary surgery of their spine (Fusion or instrumentation)

Exclusion Criteria:

- Diagnosis of scoliosis other than degenerative or idiopathic (i.e. paralytic/neuromuscular, congenital
- Undergoing revision (Fusion / Instrumentation)

EOS exclusion Criteria:

- Patients younger than 7 years old
- Patients with supernumerary vertebrae (one extra or one less thoracic or lumbar vertebrae)
- Patients with hemivertebrae
- Insufficient quality of images to perform the 3D modeling with sterEOS software

Note: Every patient who only meets the EOS exclusion criteria will be automatically transferred in the A cohort if they are over 18, and in the C cohort if they are younger than 18 years old.

Research Design & Methods:

All patients meeting the inclusion criteria will be offered enrollment into the study.
Cases will be collected over a 6 – 18 months interval.

Although there will be no direct benefit or anticipated impact on the care of patients enrolled in this study, it is reasonable to expect that the results will prove beneficial to patients undergoing spine surgery in the future.

Patient Enrollment:

Every steps outlined below are mandatory and must be adhered to for successful patient enrollment into study:

- For the 4 cohorts
    a. Signed consent
    b. Complete preoperative data (planning)
    c. Surgical treatment
    d. Complete surgical data
    e. Complete postoperative data

Post-operative acquisitions will be performed at one week and then 3-4 months after the surgery.

Data Collection:

The data form(s) to be utilized for the purpose of collecting specific data and will not contain patient identifiable information. Data collection schedule as follows:

Current practice planning	Preop	Periop	1 week Post op	3–4 months post-op
Patient Demographics	X			X
HRQL Questionnaires/Pain Tools (SRS22r, SF-12, ODI, NDI, EQ5D)	X			X
Clinical Exam	X			X
3D modeling				
Radiographic Data (Coronal & Sagittal EOS Films)	X		X	X
Surgical Data		X		
2D Planning questionnaire	X			
3D Planning questionnaire				
Surgical questionnaire		X		
Post-op questionnaire (2 questionnaires)			X	

Current practice planning + 3D parameters from 3D modeling	Preop	Periop	1 week Post op	3–4 months post-op
Patient Demographics	X			X
HRQL Questionnaires/Pain Tools (SRS22r, SF-12, ODI, NDI, EQ5D)	X			X
Clinical Exam	X			X
3D modeling	X			
Radiographic Data (Coronal & Sagittal EOS Films)	X		X	X
Surgical Data		X		
2D Planning questionnaire	X			
3D Planning questionnaire	X			
Surgical questionnaire		X		
Post-op questionnaires (2 questionnaires)			X	

All available information from the original source documents will be centralized into global spreadsheets in order to perform the preliminary and final analyses.

DATA MANAGEMENT AND ANALYSIS

Demographic and HRQOL (see appendix 1)

Demographic data (Age, Weight, Height,…), Health Related Quality Of Life (HRQOL) data, and pain diagram data (VAS) will be collected in order to quantify the subjects' self-reported pain, level of disability and physical activity.

Radiographic data

A full-length EOS exam from head to feet will be performed in the standing position. De-identified images will be transferred to the EOS 3D services through the 3D Services Platform (*https://eos3dservices.com/*). Trained and skilled technicians will perform the 3D reconstructions of the spine, the pelvis and lower extremities, using spine workflow and global Postural Assessment workflow on sterEOS software. 3D models will be made available for visualization and validation by the surgeons in the spineEOS software, which is available through the 3D Services Platform (FDA-approved, HIPAA-compliant). 2D parameters will be obtained in the actual standard of care.

- **2D parameters**
  - Sagittal plane
    - Pelvic Incidence, Pelvic Tilt, Sacral Slope
    - Lumbar lordosis (L1-S1 and maximal)
    - Thoracic kyphosis (T4-T12 and maximal)
    - Thoraco-lumbar alignment
    - Cervical alignment
    - T1 and T9 spino-pelvic inclination
    - Retro and spondylolisthesis
    - C7SVA
    - Global Cranial-Hip and Cranial-Ankle alignment
  - Coronal plane
    - Cobb angles
    - Rotatory subluxations
    - C7 plumbline
    - AVT Thoracic
    - AVT Lumbar

- **3D parameters**
  - Same parameters described in 2D but also measured in 3D
  - Vertebrae orientations in the three planes
  - Intervertebral rotations in the three planes
  - Sagittal balance parameters : SVA, CAM-HA, Spino sacral angle, T1 and T9 tilt, FBI
  - …

Data Analysis and Data Monitoring

This pilot study is mainly an observational study. The aim of the study is only to observe the value of additional information provided by 3D modeling with sterEOS software.

At the end of the 6 first months of the study, a first data analysis will be performed at Columbia with the available data in order to have some preliminary results. The final data analysis will be performed at the end of the data collection, when every patients enrolled will have the full assessment (preop, periop and post-op data). This analysis will be performed at EOS Imaging with the shared data provided by Columbia.

Descriptive analysis (mean, range and standard deviations) will be calculated for all the parameters and HRQOL data with Excel software. Correlations will be performed using Pearson correlation coefficient, and Student's t-Test will be utilized to determine if these correlations are significant, with significant p-value set at 0.05.

Data storage

The research team will follow rigorous procedures to protect confidentiality of study participants. Access to identifying information will be limited to those whose project roles demand it, and only for the period of time in which they need it. All electronic data will be stored on encrypted endpoint devices and a certified multi-user system.

Once the relevant research data is collected, the direct identifiers will be removed from the research data to maintain protection of PHI, the subject's data will be linked to a Study ID Number, and the link to direct identifiers will be stored in a separate master list only accessible by study personnel listed on this protocol. At completion of the study, the link to direct identifiers will be destroyed.

At no time and under no circumstances will any directly identifiable patient information or data be shared with any outside institutions not otherwise specified, individuals, or other entities. All funding agencies, the Columbia University Institutional Review Board, and the US Department of Health and Human Services will have the right to inspect medical records related to this study for the purpose of verifying data and patient confidentiality practices.

Data release:

At the end of the data collection period, coded research data (global spreadsheets) will be shared with EOS Imaging France, where the link to identifiable information will remain at Columbia.

To perform the transfer from Columbia to EOS Imaging, the data will be sent via encrypted email. Patient will agree to this release as stipulated in the consent form.

Risk

No further risks for physical injury are associated with participation in this study. This study will only observe the value of additional information and will not change the current practice for all the patients enrolled.

Costs to the Subject

Any imaging and surgical component used in the present study will be considered part of the standard of care. The patient may want to discuss this with his/her insurance carrier in advance. The patient will be responsible for any co-payments and/or deductibles for services rendered.

REFERENCES