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Introduction of the Biokinemetric Triangle - a New Surrogate Parameter for Analysis of Spinal Range of Motion

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Abstract: ***Background:*** In preparation for a cervical device study (CDS) we developed a software-based surrogate model in order to analyze pre- and postoperative segmental range-of-motion (ROM) and help determine the optimal height of cervical implants. Besides eliminating surgeon's bias during intraoperative device-height choice, this software-based approach to spinal implantation surgery aims to reduce postoperative neck pain. In this study we evaluated the feasibility of using this surrogate model to determine changes in pre- and postoperative segmental motion characteristics independent of surgeon-related bias of device-height choice. ***Methods:*** The software's surrogate model is based on videofluoroscopic movement recordings in addition to conventional radiographs recorded during standardized movements. Software-based evaluation of segment-specific range-of-motion (ROM) characteristics was based on the newly introduced surrogate parameter "biokinemetric triangle". Depending on changes of the triangles surface area during pre- and post-operative analysis, segment-specific ROM were determined and evaluated with regards to surgery-related ROM changes. Structural pattern recognition was employed to examine whether biokinemetric triangle based ROM analysis is able to discriminate between different implants. ***Results:*** The surrogate parameter biokinemetric triangle software plug-in allows detection of implant-specific functional alterations of segmental movement characteristics ($p<0.05$). It is a valuable follow-up parameter for the investigation of changes in the segmental motion characteristics after device implantation. ***Conclusions:*** Biokinemetric triangle analysis displays segmental motion characteristics and detects segmental changes after device implantation in CDS. Common range of motion (ROM) analysis based on angular observations requires complete movement execution in order to make significant comparisons, whereas the triangle-based analysis allows movement characterization independent of complete execution.

Keywords: *cervical discectomy, cervical prosthesis, cervical cage, biokinemetric triangle, segmental range of motion*

1. Introduction

Recently, the German Patent and Trademark Office (DPMA) has disclosed "Biokinemetrie" as a procedural method for creating improved prosthetics in spinal degeneration by the example of a medial interspinous device, designed to support

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the facet joints [23, 27]. Biokinemetrie defines the mathematical decryption of physiologic segmental movement, which may allow functional replacement of a vertebral motion-segment with a prosthetic device [7, 30, 32, 33, 34]. One possible use for the functional replacement of a spinal segment could be the desire to avoid iatrogenic adjacent level disease after stabilizing surgery. However, whether iatrogenic adjacent level disease really exists is currently still debated [26]. In order to find the answer to this question we recently started a cervical device study (CDS), which consists of two parts (PNS study NCT02936765 and PNR study NCT02936739) [24]. In the PNS study, mono-segmental cervical discectomy is followed by either implantation of an Elastic Spine PAD™ (FH Orthopedics®, France) or the implantation of a polyetherketoneketone (PEKK) cage (Squale™ manufactured by OSD® orthopaedic & spine development, France). In the PNR study, mono-segmental cervical discectomy is followed by either implantation of an Elastic Spine PAD™ or implantation of a cervical prosthesis (Rotaio™ manufactured by Signus®, Germany). The three devices used in the two studies are technically different. The PEKK cage is expected to induce rigid bony fusion, the Elastic Spine PAD™ can be considered as an elastic cage resulting in dynamic rigidity of the implanted segment, and the Rotaio™ prosthesis is based on a slipping hinge joint and may therefore preserve segmental movement in a mechanically pre-defined manner. The underlying hypothesis of the study is: if the segments adjacent to the implanted devices degenerate significantly different during follow-up this would be due to device-specific differences [29]. Primary clinical endpoint of the studies is the Neck Disability Index. However, since postoperative neck pain is significantly influenced by implant-height [15], we aimed to eliminate this bias via preoperative software-based objective determination of the optimal device height for each patient. Therefore, the simulation software introduced in the current study was designed to propose the height of the implant and takes into consideration the current state of degeneration in order to avoid device-induced overcorrection [3, 4, 6, 9, 28, 31]. The algorithm of the software is hereby based on the assessment of predefined standardized spinal videofluoroscopic movement recordings, which were interpreted as cinematographic investigations [1, 2, 13, 16, 19]. During assessment of patients, the software can then combine these predefined datasets with data acquired from standard movement radiographs (extension, neutral and flexion) in order to approximate patient-specific segmental ROM and suggest the implants optimal height. Postoperatively the same software-based evaluation is used for follow-up evaluation of surgery-related changes of segmental ROM, thereby also allowing continuous improvement of the software's algorithm with the ultimate goal to improve patient outcome.

2. Method

To describe the functional alteration of adjacent levels after implantation of a specific device the surrogate parameter "biokinemetric triangle" was integrated into the software. This element has already been shortly mentioned in a previous proceeding [26]. Hereby, the triangle's baseline is defined by the lower vertebra's upper plate and reaches from the leading edge of the lower vertebra (1st point) to the ascending lateral facet (2nd point). The 3rd point is defined by the rear edge of the upper vertebra at the roof of the neuroforamen (Fig. 1). Because its baseline is fixed, the triangle only changes its height during movement. The change of the triangles' height defines the movement of the 3rd point at the roof of the neuroforamen with respect to the underlying vertebra, thus characterizing the segmental movement pattern. The characteristic curves displayed in the diagram (Fig. 2) result from the change of the triangles' surfaces area (Fig. 3) during the spine's movement (Fig. 4) and indicate (from left to right) changes in segmental motion from extension (left) to flexion (right). To further define inter-segmental communicating movement patterns, the algorithm additionally calculates the ratio between ΔS and the percentile segmental position within the total movement-sequence (ΔS / Δ%). The software determines the triangles surface every 2.5% of the full movement-sequence, thus movement characteristics of each segment are represented by three real (extension, neutral and flexion) and thirty-eight virtually calculated measurements.

Software-based cervical movement measurements are performed in all patients of the CDS pre-

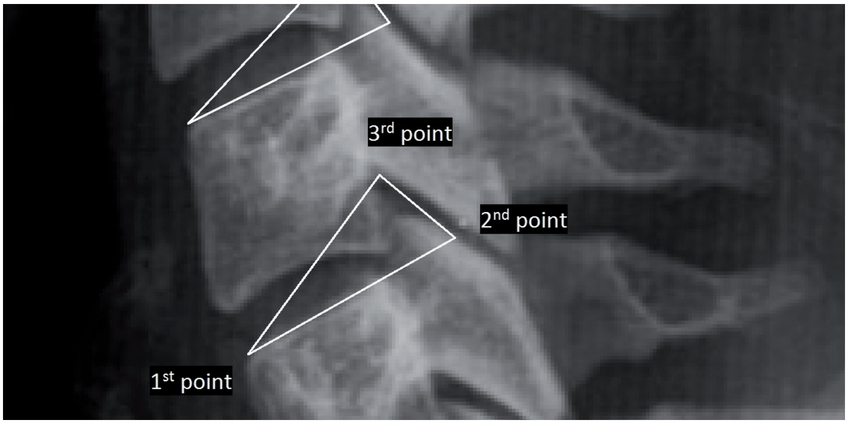

Fig. 1: *Definition of the triangle configuration for biokinemetric characterization of the segment.*

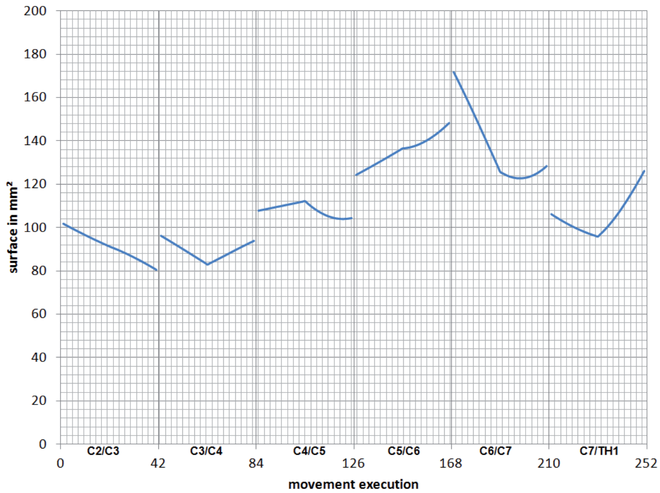

Fig. 2: *Movement characteristics of the different levels expressed via change of the triangle's surface.*

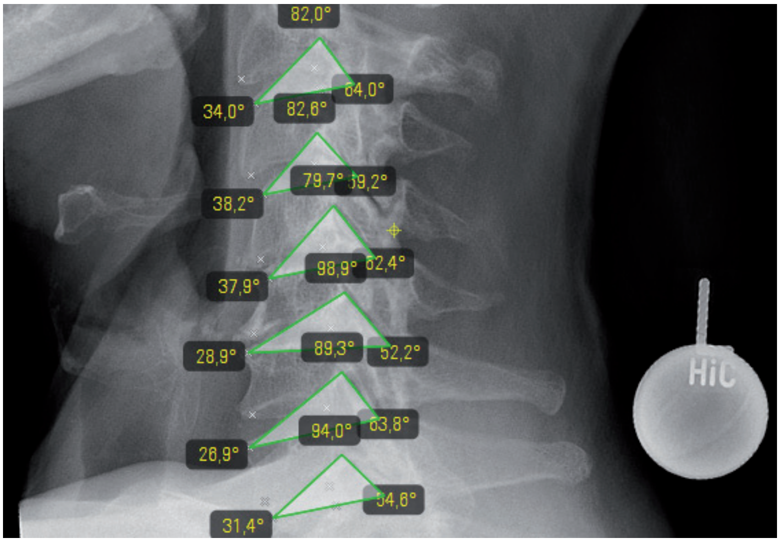

Fig. 3: *Segmental projection of the triangles which generate the curves in Fig. 2 due to the change of their surface area during the movement. Preoperative values of respective triangles, before implantation of SqualeTM in C5/C6.*

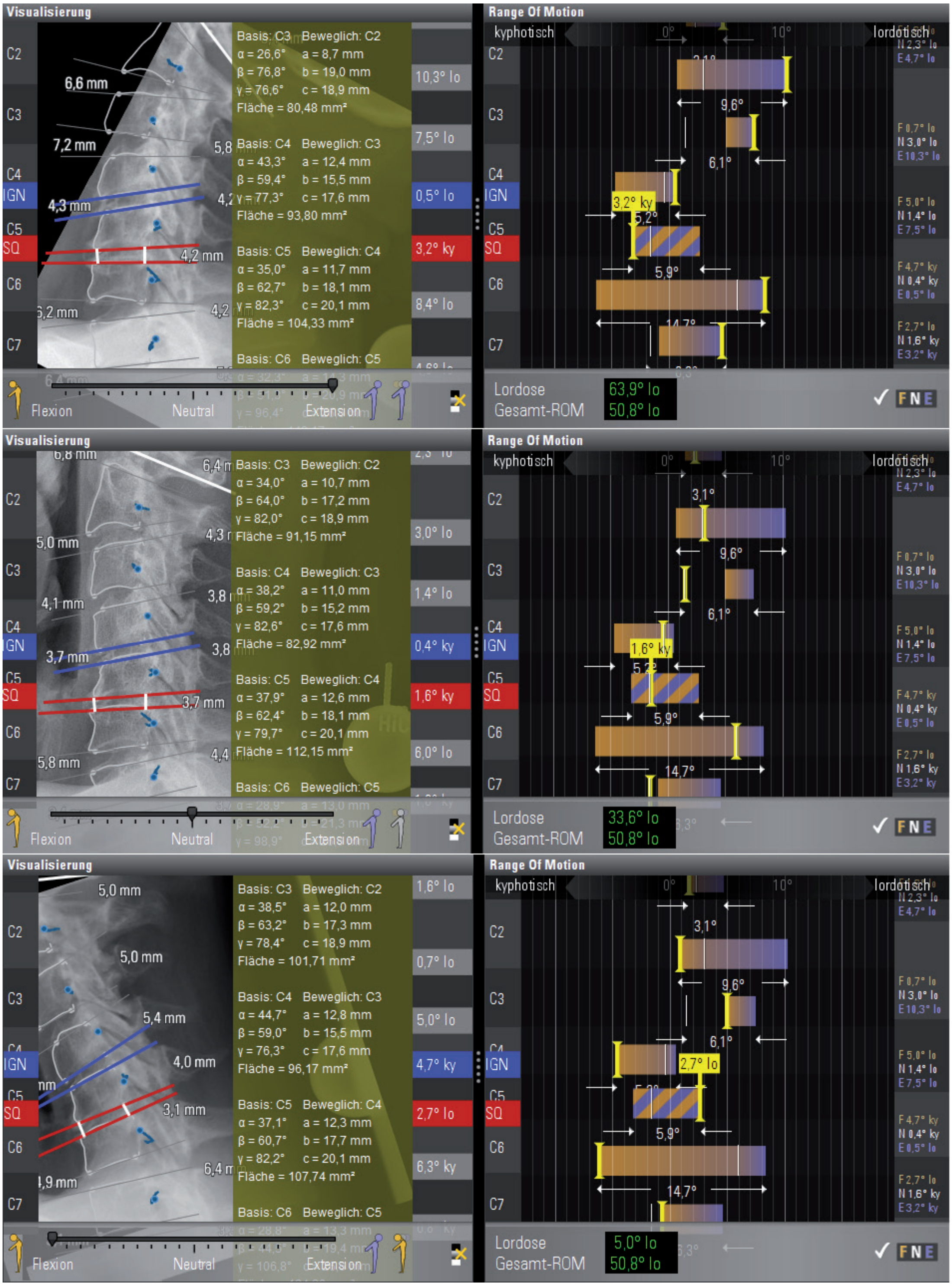

Fig. 4: *Preoperative movement-simulation of the considered spine with common range of motion analysis.*

operatively and will be acquired at three-month, at six-month and at one year following surgery, thereby assessing in detail the inter-segmental communication after device implantation. Structural pattern recognition is used to investigate whether the biokinemetric triangle analysis is able to discriminate between different implants with regards to patient-specific changes in adjacent segmental motion.

The decisive advantage of the biokinemetric triangle is that motion characteristics can be compared with each other at different examination times even when the motion is not performed in full completion [24, 25].

3. Results

A Software-based evaluation of cervical anatomy and movement-patterns helped the surgeon to preoperatively determine the implants device height. Preliminary follow-up via the software's biokinemetric triangle plugin additionally demonstrated significant changes in postoperative segmental movement characteristics ($p<0.05$). Moreover, the recorded postoperative data demonstrates device-specific changes of adjacent level ROM, which propagated over several adjacent levels (Fig. 5 in comparison with Fig. 2). The biokinemetric triangle was validated as an appropriate surrogate parameter for monitoring the change of segmental functionality in the follow-up of CDS patients (Fig. 6, 7).

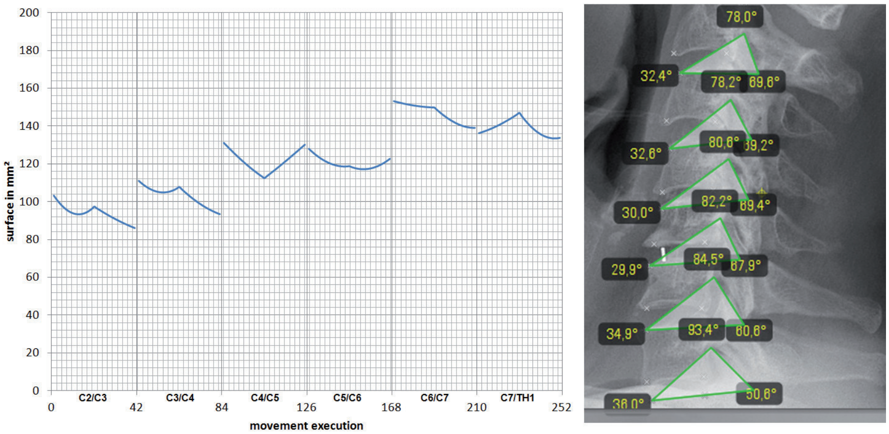

Fig. 5: *3-month follow-up after implantation of Squale™ in C5/C6.*

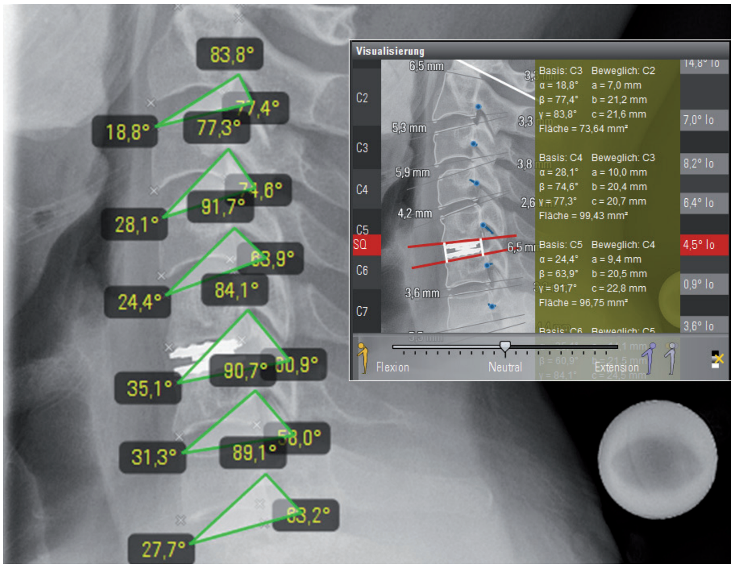

Fig. 6: *3 month follow-up after implantation of Rotaio™.*

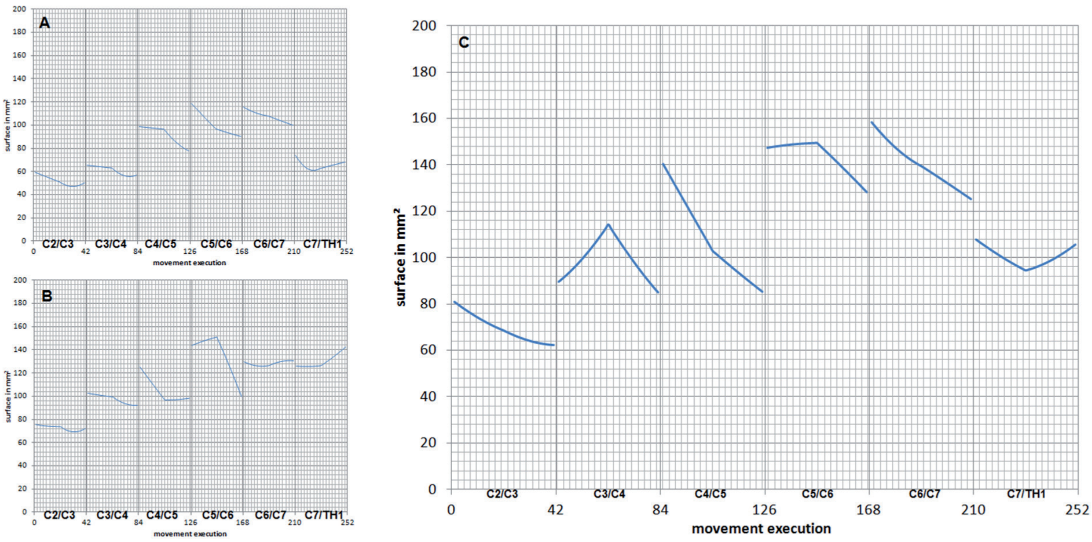

Fig. 7: *Before implantation of Rotaio™ in C5/C6. B: 3-month follow-up after implantation of Rotaio™ in C5/C6. C: 6-month follow-up. The triangle's consideration is able to identify the implanted device via pattern recognition based on the displayed changing motion characteristics. In the case of the Rotaio™ prosthesis, this alteration is particularly pronounced (B). Therefore, in the further course (C), there is a physiological restriction of the non-physiological movement and consequent increasing stress in the adjacent segments.*

4. Discussion

In this study we introduce the biokinemetric triangle and demonstrate several representative examples of a software-based approach to assess cervical anatomy and segmental motion patterns, helping surgeons during preoperative device choice and postoperative functional follow-up. We outline the fact that cervical device implantation leads to significant changes in postoperative movement characteristics not only in the operated, but also in adjacent segments and further found that changes propagated over several adjacent levels. Patient-specific segmental degeneration may require patient-tailored device choices, with the intent to restore segmental movement patterns as close as possible to physiological ROM and prevent long-term disability. The ability to integrate software-based ROM-analysis into the surgical preparation and follow-up therefore presents a valuable opportunity to help surgeons as well as device-manufacturers to objectively optimize device-choice and -properties according to patient-specific needs.

The human spine is a complex structure of mechanically-linked segments, in which segment-specific ROM is determined by composite-movement patterns thereby differing from most other joints of the body. Software-based analysis using the biokinemetric triangle is able to display movement characteristics without confusing angle considerations and aims to describe segmental movement by focusing analysis on a single point at the roof of the neuroforamen (3rd point, height of triangle) [25]. The bony real analog of this point of interest moves around the nerve root in a specific manner, which could be described as a slipping or translational movement due to it's instantaneous center of rotation [30]. Physiologically, this movement-pattern prevents nerve-root impingement at the neuroforamen. In comparison to common ROM analysis, which is based on angular observations, the biokinemetric triangle based observation does not require complete movement execution. In the CDS the biokinemetric triangle plugin is currently used to characterize cervical movement based on sagittal imaging data only. However, in order to further extent accuracy during movement analysis and device-specific prediction of postoperative ROM changes, it will likely be beneficial to further integrate the anterior-posterior (a-p) plane into the biokinemetric analysis [26]. Therefore our current software development aims to transition from 2D plane radiographic analysis to 3D computed tomography based data acquisition [22].

5. Conclusion

The aim of the introduction of the biokinemetric triangle is to mathematically approximate the movement patterns of the spine in order to facilitate an improved spinal prosthetic restoration [23]. Even though our preliminary CDS data demonstrates that there are device-specific changes in postoperative segmental and adjacent level ROM, it is currently too early to determine whether these variations will translate into significantly different radiological and clinical courses of degeneration. Long-term patient follow-up will help to further improve the software's algorithm and determine it's predictive value regarding patient-outcome.

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