ROTAIO

https://signus.com/intl/products/portfolio/rotaio-cervical-prosthesis.html

The ROTAIO® artificial cervical disc prosthesis is an unconstrained implant with a variable center of rotation aiming at physiological movement.

The instantaneous center of rotation (iCOR) of a motion segment has been shown to correlate with its total range of motion (ROM). Importantly, a correlation of the correct placement of cervical total disc replacement (cTDR) to preserve a physiological iCOR has been previously identified. However, changes in these parameters and the corresponding clinical relevance have hardly been analyzed. This study assesses the radiological and clinical correlation of iCOR and ROM following cTDR.

A retrospective multi-center observational study from Innsbruck, Greifswald, Munich, Bern was conducted and radiological as well as clinical parameters were evaluated preoperatively and 1 year after cTDR with an unconstrained device. Radiographic parameters including flexion/extension X-rays (flex/ex), ROM, iCOR and the implant position in the anterior-posterior direction (IP ap), as well as corresponding clinical parameters [(Neck Disability Index (NDI) and the visual analog scale (VAS)] were assessed.

57 index segments of 53 patients treated with cTDR were analyzed. Pre- and post-operative ROM showed no significant changes (8.0° vs. 10.9°; $p > 0.05$). Significant correlations between iCOR and IP (Pearson's R: 0.6; $p < 0.01$) as well as between ROM and IP ap (Pearson's R: - 0.3; $p = 0.04$) were identified. NDI and VAS improved significantly ($p < 0.01$). A significant correlation between NDI and IP ap after 12 months (Pearson's R: - 0.39; $p < 0.01$) was found.

Implantation of the tested prosthesis maintains the ROM and results in a physiological iCOR. The exact position of the device correlates with the clinical outcome and emphasizes the importance of implant design and precise implant positioning. [1)].

Multicenter prospective trial

120 patients (72 females and 48 males with median age of 43.0 years [23-60 yrs] underwent ACDA (ROTAIO®, SIGNUS Medical, Alzenau, Germany) and were prospectively followed for 24 months. Preoperative complaints were mainly associated with radiculopathy (n = 104) or myelopathy (n=16). There were 108 monosegmental and 12 bisegmental procedures including 6 hybrid constructs. Clinical outcome was evaluated at 3, 12 and 24 months in 100%, 96% and 77% of the cohort by VAS, NDI, WL-26, Patient`s Satisfaction Index (PSI), SF-36, Nurick Score, mJOA, Composite Success Rate, complications, patient`s overall satisfaction and analgesics use.

Results: Highly significant clinical improvements were observed according to NDI and VAS ($P < .0001$ (arm); $P < .001$ (neck); $P = .002$ (head)) at all time points. Analgetic use could be reduced in 87.1 to 95.2%. Doctor`s visits have been reduced in 93.8% after 24 months. Patient`s overall satisfaction was high with 78.4 to 83.5% of patients. The composite success rate was 77.5% after 12 months and 76.9% after 24 months. There were no major complications in this series. Slight subsidence of the prosthesis was observed in 2 patients and 3 patients demonstrated fusion after 24 months. 2 patients

developed symptomatic foraminal stenosis, so that implant removal and fusion was performed resulting in a revision rate of 1.7% in 2 years.

Conclusion: The ROTAIO® cervical disc prosthesis is a safe and efficient treatment option for symptomatic degenerative disc disease demonstrating highly significant clinical improvement and high patient`s overall satisfaction with very low revision rates at 2 years [2].

Case series

Twenty-seven female and 18 male patients (n = 45) with a mean age of 43.7 ± 7.8 years were prospectively followed up for a maximum of 24 month. Clinical outcomes were assessed by Neck Disability Index (NDI), visual analogue scale (VAS) scores for neck and arm pain, patients´ overall satisfaction and the usage of analgesics. Additionally, radiographic information including ROM of the functional spinal unit (FSU) and signs of adjacent segment disease were recorded.

Results: NDI and VAS scores showed significant improvement 6 months after surgery and at last follow-up ($p < 0.001$). Concerning overall satisfaction 95.7% of the patients showed good to excellent results at the last visit and a significant reduction of analgesic usage was observed ($p < 0.001$). Radiographic measurements showed a mean increase of ROM up to 8.40° in the treated FSU at last follow-up ($p < 0.001$). No signs of anterior migration or dislocation of the prosthesis and no subsidence was recorded radiographically. There were no major complications and a low rate of secondary procedures (2.2%).

Conclusion: In the 24-months follow-up the ROTAIO Cervical Disc Prosthesis provided excellent clinical and radiographical results and seems to be safe and effective for the treatment of symptomatic single-level degenerative disc disease. [3].

1)
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2)
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