Prospective Multicenter Trial of Cervical Arthroplasty With the ROTAIO® Cervical Disc Prosthesis

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Abstract

Objective

Anterior Cervical Discectomy and Arthroplasty (ACDA) is an established treatment for degenerative cervical disc disease and seems to be an alternative to fusion in minimizing the risk of Adjacent Segment Disease (ASD). The ROTAIO® cervical disc prosthesis is a novel unconstrained implant with a variable center of rotation aiming at physiological motion. The objective of this multicenter prospective trial was to evaluate clinical outcome and complications within 2 years.

Material and Methods

120 patients (72 females and 48 males with a median age of 43.0 years; range: 23 to 60 years) 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 by the Visual Analogue Scale (VAS) for head, neck and arm pain, the Neck Disability Index (NDI), the Work Limitation Questionnaire (WL-26), the Patient $sSatiactionIndex(PSI)$ and $aQualityofL$ if $eQuestio \cap aire(SF-36).TheNurickSc$ or $e, theMod$ if $iedJapa \neq seOrthopaedicAssociation S$ s overall satisfaction and the amount of analgesics were assessed.

Results

Highly significant clinical improvements were observed according to NDI and VAS (p<0.0001 (arm); p<0.001 (neck); p=0.002 (head)) at all postoperative time points. Analgetic medication could be reduced after 3 months in 91.3%, after 12 months in 87.1% and after 24 months in 95.2% of patients. Doctor`s visits for cervical spine problems have been reduced in 93.8% after 24 months.

Patient`s overall satisfaction was high after 3, 12 and 24 months with 83.5%, 78.4% and 79.1% of patients, while 4.1%, 6.8% and 7.0% respectively were not satisfied. 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.

Conclusion

The ROTAIO® cervical disc prosthesis is a safe and efficient treatment option for symptomatic degenerative disc disease demonstrating excellent clinical results at 2 years. Outcome proves to be stable over time with very low revision rates.

Purpose

Since its introduction in the 1950s (Smith & Robinson, 1958) Anterior Cervical Discectomy and Fusion (ACDF) has become a standard surgical procedure for the treatment of cervical disc disease in patients with radiculopathy or myelopathy. ACDF is performed to achieve neural decompression, segmental stabilization and to maintain cervical lordosis. ACDF yields good clinical outcome and high fusion rates (Fraser & Hartl, 2007) (Shriver et al., 2015). However, fusion sacrifices the mobility of the operated segment leading to increased biomechanical forces at the level of the non-fused adjacent segments und this may accelerate Adjacent Segment Disease (ASD) (Anderson et al., 2012a; Reitman et al., 2004). Anterior Cervical Discectomy and Arthroplasty (ACDA) has been introduced as an alternative that preserves segmental mobility of the operated segment aiming at decreasing the risk of ASD. Although recent randomized clinical trials (Coric et al., 2011; Heller et al., 2009; Mummaneni et al., 2007; Murrey et al., 2009; Sasso & Best, 2008) have compared both techniques, this issue is still controversially debated (Anderson et al., 2012a; Fallah et al., 2012; Shim et al., 2006; Song et al., 2011) (Bartels et al., 2010) and mid- to long-term results are sparse. Currently, there are many disc prostheses with different biomechanical properties commercially available, which claim to imitate physiologic motion. Standard ball and socket designs and (semi-) constrained devices, however, don´t allow uncoupled translation and are thus thought to force the facet joints into non-physiologic movements. As this may interfere with successful outcome over time, our group focused on an unconstrained disc prosthesis with uncoupled translation. (Kang et al., 2010; Rousseau et al., 2008).

The aim of this multicenter, multinational prospective observational study was therefore to evaluate clinical outcome and complications with the newly developed artificial cervical disc prosthesis ROTAIO® (SIGNUS Medizintechnik GmbH, Alzenau, Germany) within a follow-up period of 24 months.

Materials And Methods

The study complied with the Declaration of Helsinki and was approved by all local ethics committees of the involved centers (initial approvement: Ethics Commission, Medical University Innsbruck, Austria). All patients gave written informed consent.

Patient population

Consecutive patients meeting the inclusion criteria were prospectively included from July 2014 to January 2019.

Inclusion criteria:

(2) Degenerative Disc Disease (DDD) at one or two levels between C3/4 to C6/7 and a disc height of at least 50% in comparison to other segments,

(3) no improvement of clinical symptoms after at least 6 weeks of conservative treatment or significant or progressive neurological deficits at the time of presentation,

(4) a minimum NDI of 15 points (30%).

Exclusion criteria:

1. cervical instability demonstrated on flexion / extension radiographs
2. kyphotic index segment
3. non-mobile index level and/or increased osteochondrosis in index disc / facet joints
4. previous surgery of the cervical spine

Device Design

The ROTAIO® cervical disc prosthesis (Fig.1) is used to replace the disc after anterior cervical discectomy. The aim of disc replacement is to restore disc height and to maintain physiological motion of the index segment. The ROTAIO® prosthesis is a new unconstrained implant with a variable center of rotation (COR) and uncoupled translation to enable physiological facet joint-guided motion. The prosthesis consists of a superior and an inferior end plate (Titanium alloy to ISO 5832-3), on which the sliding elements (Cobalt-Chrome alloy to ISO 5832-12) are anchored and secured by means of a fixation pin. Primary stabilization is achieved via toothed surfaces of the end plates, which are additionally blasted to increase surface area and allow rapid bony integration.

Surgical procedure

Surgery was performed by board-certified neurosurgeons who had attended manufacturer
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s instructions during slight distraction of the intervertebral space.

Clinical evaluation

All patients underwent clinical examination on the day before surgery, postoperatively prior to discharge, and 3, 12 and 24 months after surgery. In addition to a clinical examination including neurological status validated self-assessment outcome measures were used: Visual Analogue Scale (VAS) (range 0-10) for head, neck and arm pain separately, Patient`s Satisfaction Index (PSI), Neck Disability Index (NDI) (range 0-50), Work Limitation Questionnaire (WL-26), and Quality of Life Questionnaire (SF-36) (MacDermid et al., 2009) (Arumugam et al., 2013). The Nurick-Score for classification of gait disturbance and the Modified Japanese Orthopaedic Association Score (mJOA) were recorded. Complications related to the implant, fusion of the index level and surgical procedures at the index level (revision surgery) or at an adjacent level (for ASD) were recorded. A Composite Success Rate was defined as the combination of (1) improvement in NDI (≥15%), (2) stable or improved neurological status, (3) no secondary operation, (4) no implant-associated complication.

Imaging protocol

Plain anteroposterior and lateral radiographs in neutral position and lateral radiographs in flexion and extension were obtained in each patient. Furthermore, all patients underwent magnetic resonance imaging before surgery. Computed tomography was additionally applied at the discretion of the surgeon.

Statistical Analysis

Data are presented as the mean value ± standard deviation (SD) of the mean.

The trial was designed to detect an absolute difference between pre- and postoperative data. Comparisons were performed with the use of an unpaired t-test, or in case of nonparametric values with the Wilcoxon-Mann-Whitney-U test. Furthermore, X^2 was used for differentiation of categories.

Differences were considered statistically significant for two-tailed p-values <0.05 (power of 80%, maximum dropout rate of 20%). Data analysis was performed with IBM SPSS Statistics Vers. 20.0.

Results

Demographic Data

120 patients (60% female, 40 % male) with a median age of 43.0 years (range: 23 to 60 years) were included. The majority of patients underwent ACDA at the C5/6 (58.8%) and the C6/7 (49.6%) levels. Preoperative complaints were mainly associated with radiculopathy (n=104; 86.7%) or myelopathy (n=16; 13.3%). There were 108 monosegmental and 12 bisegmental procedures including 6 hybrid constructs comprised of ACDF with cage fusion and ACDA with the ROTAIO® disc prosthesis. Minimum follow-up of 12 months was available in 115 patients and 92 patients had completed 2-year follow-up.

Clinical evaluation

The median duration of symptoms amounted to 5 months. Demographics and preoperative symptoms are listed in table 1. There were some differences

ic (MP) patients.

Highly significant clinical improvements were observed for **VAS** arm ($p<0.0001$), neck ($p<0.001$) and head ($p=0.0022$) at all time points. Significant **functional improvements** were observed with a ≥15% decrease in **NDI** in ≥90% at 12 and 24 months after surgery. Differences of RP and MP are noticed in table 3.

The neurological status according to muscle **strength** and **mJOA** remained stable or improved in 92.5% and 96.9% respectively. The **composite success rate** was 77.5% after 12 months und 76.9% after 24 months.

Analgesic medication could be reduced after 3 months in 91.3%, after 12 months in 87.1% and after 24 months in 95.2% of patients, but increased in 8.8%, 12.9% and 4.8%, respectively. Preoperatively, the analgesics consumption was significantly higher in the RP group than in the MP group (see table 1). As expected, improvement and success rate tended to be more pronounced in the RP group.

The **WL-26** clearly demonstrated a reduction of work limitations ($p<0.0001$ at 3, 12 and 24 months). Health-related Quality of Life (**SF-36**) revealed a highly significant improvement ($p<0.0001$) for the following items within 3, 12 and 24 months: body function, social function, psychologic well-being, physical pain, vitality, and overall health perception.

Patient`s overall satisfaction** was high after 3, 12 and 24 months with 83.5%, 78.4% and 79.1% of patients, while 4.1%, 6.8% and 7.0% respectively were not satisfied. **Doctor`s visits for cervical spine problems have been reduced in 93.8% after 24 months and increased in 6.2%.

Complications

There were no major complications in this series. Temporary morbidity related to the anterior cervical approach but not the implant per se, like recurrent nerve palsy and significant dysphagia, occurred in 2 patients. Initially, 2 patients experienced intermittent and transient cracking noises. Slight subsidence of the prosthesis was observed in 2 patients and 3 patients demonstrated fusion after 24 months. 2 patients developed clinical problems associated with foraminal stenosis after 3 and 9 months, respectively, so that implant removal and fusion was performed. Revision rate thus amounted to 2% at the index level and no procedures at the adjacent levels within 2 years.

Discussion

Anterior Cervical Discectomy and Fusion (ACDF) is a standard procedure for the treatment of degenerative cervical disc disease. Based on the notion that preserving motion reduces the risk of Adjacent Segment Disease (ASD) (Chang et al., 2007; Robertson et al., 2005), Anterior Cervical Discectomy with Arthroplasty (ACDA) has been introduced as an alternative to fusion in the 1990´s. Although clinical outcome is well documented for both techniques (Anderson et al., 2012a; Fallah et al., 2012), some patients will experience persistent or increasing symptoms over time.

Adjacent Segment Disease

Despite its well documented benefits, ACDF may cause ASD in mid- and long-term follow-up (Goffin et al., 2003; Ishihara et al., 2004; Katsuura et al., 2001; Kim et al., 2009; Song et al., 2011; Yao et al., 2015). Biomechanical studies have shown increased intradiscal stress and motion compensation in the levels adjacent to the fusion site (Eck et al., 2002; Schwab et al., 2006) with a change of the center of rotation in adjacent levels postoperatively (Dvorak et al., 1993) (Eck et al., 2002) (Anderson et al., 2012b). Although this is considered by some authors to be the underlying cause for ASD, it is still controversial if this is attributable to the biomechanical effects of fusion or to the natural history of cervical degeneration (Anderson et al., 2012a; Bartels et al., 2010; Seo & Choi, 2008).

Reoperation due to ASD has been documented at a rate of 2.9% annually after ACDF (Hilibrand et al., 1999). ACDA is considered as an alternative to ACDF preserving normal cervical kinetics and biomechanics (Goffin et al., 2002). Thus, the rate of additional surgeries may be reduced with less stress on adjacent levels using ACDA (Upadhyaya et al., 2012) (Traynelis, 2006). The pooled surgery rate for ASD after disc prosthesis (ACDA) was 3.8% (0.9 -7.6%) within a follow-up of up to 84 months summarizing 13 randomized controlled trials (RCT) (Kang et al., 2015). Although clinical short-term results are satisfactory (Goffin et al., 2003; Heller et al., 2009; Murrey et al., 2009), there are only a few studies reporting mid- to long-term results (Ding et al., 2012; Garrido et al., 2010; Goffin et al., 2010; Walraevens et al., 2010). Garrido et al (Garrido et al., 2010) reported improved functional outcome for ACDF and ACDA on 24 and 48 months follow-up with no degradation of the outcome measures between 2 and 4 years after surgery. This is in concordance with the results of Goffin et al. (Goffin et al., 2010), who reported consistent if not improved clinical results at 4- and 6-years follow-up compared to the 1- and 2-years postoperative results. Our study supports these data that patients improved significantly after surgery and the clinical results remained stable on mid-term follow-up.

The protective effect of ACDA on the adjacent discs remains controversial. In the single level arm of their prospective cohort study, Kim et al. (Kim et al., 2009) observed ASD in 13% of all patients treated with ACDA compared to 23% in the ACDF group at a median follow-up of 19 month. Walraevens et al. reported ASD in the adjacent upper and lower segment to the operated site for up to 8 years after ACDA (Walraevens et al., 2010). Similar observations were made by Ding et al. (Ding et al., 2012). They observed mild ASD in the adjacent levels in approx. 23% of all patients. The degeneration mainly manifested as new formation or enlargement of an anterior osteophyte. However, no degeneration in clinical outcome occurred due to the lack of a direct relation between radiographic and clinical ASD (Ding et al., 2012). In our cohort with the new ROTAIO® prosthesis, no patient required adjacent level surgery within 2 years.

Quality of motion

After ACDA emphasis is often placed on presence and magnitude of motion as assessed by ROM, while quality of motion by parameters like instantaneous COR, COR, and instantaneous axis of rotation has just recently been identified as important for evaluating changes in the cervical motion pattern (Anderst et al., 2013; Guo et al., 2019; Jonas et al., 2018; Penning, 1988). Anderst et al. demonstrated that the instantaneous COR was generally fixed in the longitudinal direction, but it translated in the anterior-posterior direction during flexion-extension (Anderst et al., 2013). If translation is not adequately possible, non-

physiologic stress on the facet joints at the index level ensues, which may cause facet joint syndrome, as it has commonly been seen in lumbar disc arthroplasty. Liu et al. evaluated the instantaneous COR located at the superior half of the lower vertebral body height and the posterior half of its width, and changing with age (Liu et al., 2014). It has been postulated that these further findings should be considered in clinical practice and when designing disc prostheses (Guo et al., 2019).

Although the overall effectiveness of ACDA has already been demonstrated, the kinematic properties of the various designs differ substantially (Galbusera, Bellini, Brayda-Bruno, et al., 2008; Kang et al., 2010). The Bryan disc prosthesis with its almost unconstrained design retained kinematic motion adequately (Pickett et al., 2005; Powell et al., 2010; Ryu et al., 2013), (Fleck et al., 2017) (Kowalczyk et al., 2011), yielding a near-physiological rotation at the index level (Galbusera, Bellini, Raimondi, et al., 2008). Ball-and socket designs like the Prestige LP (semiconstrained design) and the Prodisc-C (semiconstrained with fixed axis of rotation), however, did not fully restore normal mobility in view of ROM and COR, which may cause secondary problems over time (Rousseau et al., 2008). Particularly neck pain can be an ongoing problem after ACDA as a result of abnormal forces and load on the facet joints.

As standard ball and socket designs and (semi-) constrained devices do not allow uncoupled translation and are thus thought to force the facet joints into non-physiologic movements as mentioned above. As this may interfere with successful outcome over time, our group focused on an unconstrained disc prosthesis with uncoupled translation. The low revision rate and the stable clinical results over time in this series seem to support these considerations.

Clinical Outcome

In 2016, preliminary clinical and radiographic results with the ROTAIO® cervical prosthesis demonstrated excellent results (Obernauer et al., 2016). Our present results with more than 100 patients in a multicenter prospective trial confirm these findings with excellent clinical outcome. Pain relief, reduction of analgesics consumption, functional improvement, reduction of disability, patient satisfaction and quality of life were found to be very high and at least comparable to previous IDE trials. Revision rate was very low and no implant failure was observed. No surgical procedure due to ASD was performed within 2 years.

Nevertheless, longer follow-up is necessary to prove durability and functionality of the prosthesis. In view of our current data, however, the ROTAIO® prosthesis is a suitable alternative to ACDF and other available prostheses. The particular biomechanical characteristics with uncoupled translation and a variable center of rotation may allow physiological cervical spine motion with low fusion and ASD rates.

Limitations

This prospective observational multicenter study of consecutive patients has received research support by the manufacturer, although clinical data was assessed and analyzed by the investigators. The study was not intended to compare the ROTAIO® results to ACDF or other prostheses. Follow-up is currently limited to 2 years, so that long-term sequelae cannot yet be adequately monitored.

Conclusion

The ROTAIO® cervical disc prosthesis with its unconstrained design with uncoupled translation and variable center of rotation is a safe and effective treatment option for symptomatic degenerative disc disease. Good to excellent clinical results and very low secondary surgery rates after a follow-up of 24 months could be demonstrated in this prospective, observational study.

Abbreviations

ACDA	anterior cervical discectomy and arthroplasty
ACDF	anterior cervical decompression and fusion
ASD	adjacent segment disease
COR	center of rotation
DDD	degenerative disc disease
FSU	functional spinal unit
MP	myelopathy
NDI	neck disability index
n.s.	not significant
NSAID	non-steroidal anti-inflammatory drugs
PSI	patient`s satisfaction index
RCT	randomized clinical trial
ROI	region of interest

RP	radiculopathy
SF-36	short form -36
VAS	visual analogue scale
WL-26	work limitation
QoL	quality of life

Declarations

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Disclosure

The authors´ institutions have received funding to conduct this trial. CT, CU, RG and JUM are consultants to SIGNUS Medizintechnik GmbH.

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Ethics: The study complied with the Declaration of Helsinki and was approved by all local ethics committees of the involved centers (initial approvement: Ethics Commission, Medical University Innsbruck, Austria). All patients gave written informed consent.

Data transparency: There is availability of data and material on demand.

Code availability: Software application or custom code: not applicable.

Author`s contribution: All authors meet all 3 of the following conditions in accordance with the “Consensus Statement on Surgery Journals Authorship—2005”:

1) Authors make substantial contributions to conception and design, and/or acquisition of data, and/or analysis and interpretation of data;

2) Authors participate in drafting the article or revising it critically for important intellectual content; and

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Tables

Table 1: demographics and preoperative symptoms

	%	X^2 (p)	Radiculopathy (RP)	Myelopathy (MP)	overall
age (median) (yrs)		0.1273	42.7 ± 8.4	39.2 ± 7.5	43 (23-60)
female	60.0				
male	40.0				
leading symptoms (RP vs. MP)			87%	13%	
ASA (I-II)	80.7				
ASA (III)	19.3				
VAS overall		0.1120	5.9 ± 2.4	4.7 ± 2.0	
daily analgetics	84	0.0479	87%	67%	
doctor`s visits (≥ monthly)	51				
physiotherapy		0.0577	68%	30%	
alcohol		0.0225	51%	11%	
smoking	42				

Table 2: *clinical results (focusing on visual analogue scale (VAS) and patient`s satisfaction index (PSI)*

	preoperative	3 months	12 months	24 months
VAS overall (0-10)	6.5 ± 2.2	- 4.5 ± 2.8	- 4.2 ± 3.1	- 4.4± 2.7
VAS head (0-10)	3.0 ± 2.8	- 1.6 ± 2.6	- 1.3 ± 2.9	- 1.0 ± 3.1
VAS neck (0-10)	5.7 ± 2.4	- 3.8 ± 2.5	- 3.7 ± 2.9	- 3.4 ± 2.7
VAS arm (0-10)	6.1 ± 2.6	- 4.4 ± 3.1	- 4.1 ± 3.0	- 4.3 ± 3.0
PSI (satisfied vs. nonsatisfied)	-	83.5% vs. 4.1%	78% vs. 7%	79% vs. 7%

Table 3: *functional outcome*

	Radiculopathy (RP) (%)	Myelopathy (MP) (%)	RP and MP (%)	Significance (p) (X^2)
12 months				
NDI (decrease ≥ 15%)	*92.6*	*70*	*90.0*	*0.02*
strength and mJOA (stable or improved)	*91.4*	*100*	*92.5*	*0.34*
complication	*6.3*	*9.1*	*6.6*	*0.75*
composite success rate	*80*	*60*	*77.5*	*0.16*
24 months				
NDI (decrease ≥ 15%)	*93.0*	*75.0*	*90.8*	*0.10*
strength and mJOA (stable or improved)	*96.5*	*100.0*	*96.9*	*0.59*
complication	*8.9*	*7.7*	*8.7*	*0.99*
composite success rate	*78.9*	*62.5*	*76.9*	*0.30*

Figures

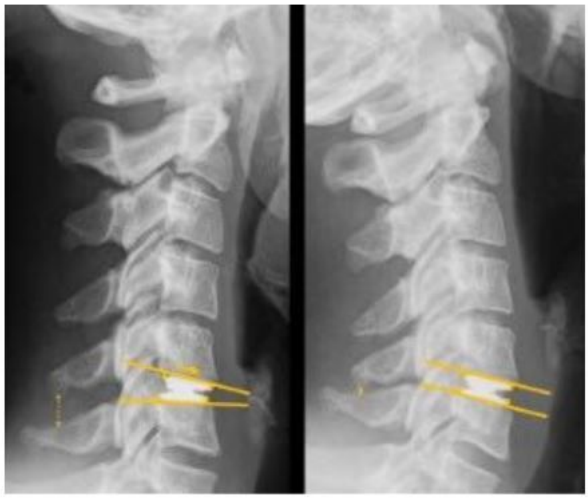

Figure 1

The ROTAIO® cervical disc prosthesis allows uncoupled anterior translation upon flexion and posterior translation upon extension mimicking natural disc motion.