Original Study

Clinical experience and two-year follow-up with a one-piece viscoelastic cervical total disc replacement

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Background: The purpose of this study is to present clinical outcome data from a 2-year post-market study of a viscoelastic one-piece cervical total disc replacement (TDR) in Europe.

Methods: Thirty-nine patients were implanted at five surgical sites in an European post-market clinical study. Clinical outcomes included improvement of neck disability index (NDI) and visual analog scale scores for neck and arm pain from baseline to 2-year follow-up, neurological examinations, patients view on the success of surgery, complications, and subsequent surgical interventions.

Results: Thirty patients had the Freedom® Cervical Disc (FCD) implanted at a single level, and nine patients were implanted at two adjacent levels. The population had a similar distribution of male [20] and female [19] subjects, with a mean age of 45 years. All self-administered outcome measures showed significant clinically important improvements from baseline to the 2-year follow-up. Mean preoperative NDI score improved from 48% to 20%, 13%, 8%, 6% and 4% at 6 weeks, 3, 6, 12, and 24 months, respectively. Average preoperative visual analog scale (VAS) scores of the neck, right and left arm pain intensity and frequency showed significant improvement. All neurological outcome measurements showed immediate improvement from preoperative values and continued improvement throughout 2 years follow-up. From pre-op to 24 months, neurological deficits declined in the population from 21% to 6% for reflex function, 62% to 17% for sensory function, and 38% to 3% for motor function. No patients experienced a deterioration in any measured outcomes compared with the preoperative situation. Patient satisfaction increased over 2 years post-op, with 83% of patients responding that they would "definitely" choose to have the same treatment for their neck/arm condition and another 11% responding that they would "probably" choose to have the same treatment.

Conclusions: The FCD performs as expected in patients with single-level and two-level degenerative disc disease.

Keywords: Cervical spine; total disc replacement (TDR); viscoelastic

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Introduction

Cervical total disc replacement (TDR) began in Europe and Australia in the 1990s. There has been a plethora of TDR designs from the very simple to the very complex in an attempt to simulate normal intervertebral disc function by preserving motion. The success of hip and knee replacement for disorders previously treated with fusion of the joint is at least partially responsible for not only the surge in interest for TDR but many of the early designs. However, hips and knees differ vastly from the intervertebral disc in their energy absorption and kinematics.

The earliest and many of the current cervical TDR designs are uni-articular or bi-articular. Some are metal-on-metal ball-in-trough designs such as the Prestige ST and Prestige LP (Medtronic) and Kineflex-C (Spinal Motion). Others are metal-on-plastic designs with one or two ball-in-socket articulations such as ProDisc C (DePuySynthes), PCM (Nuvasive), Discover (DePuy), Mobi-C (Zimmer Biomet), Secure-C (Globus Medical), ActivC (B Braun) and Synergy (Synergy). The DiscoCerv device (Alphatec) is comprised of titanium plates with a ceramic-on-ceramic articulation. Articulated TDRs have demonstrated their clinical utility in many trials, and non-inferiority to anterior cervical discectomy and fusion (ACDF) is well established (1-25). Studies also show maintenance of disc space height and motion at the operated level. Additionally, secondary surgeries occur less after TDR than ACDF (6,26,27).

However, articulated designs have biomechanical limitations. None have the shock absorption provided by a viscoelastic polymer. The non-constrained or semi-constrained designs do not deliver the stability provided by a healthy disc, and lead to overloading of posterior elements (28). There is a good deal of analytical and clinical evidence suggesting that long-term implantation of articulating devices places the facets under abnormal and excessive loading, creating an environment for facet degeneration and reoccurrence of localized pain (29-33). Some metal-on-plastic devices have been shown to deform, fail or become impinged on one area of the core and move at only one or neither of the two articulating surfaces (34,35). Patients with metal on metal devices demonstrate increased levels of the metallic ions from the metals used to manufacture them. Although these articulating devices restore motion to the spinal segment, it is not natural motion. The lack of viscoelasticity necessary to replicate the shock absorbing function of the native disc has potentially negative effects such as facet degeneration, failure to relieve pain and diminish disability, a resultant need for revision surgery, and adjacent level degeneration.

The healthy human disc is viscoelastic and has six degrees of freedom. The natural disc provides for tri-planar (three-dimensional) motion: flexion and extension (sagittal plane); lateral bending (frontal plane); rotation, and compression (axial plane). The viscoelastic nature allows for variation in the degree of stiffness with the frequency of any load, and is compliant under loading (shock absorber).

There are several discs which incorporate a viscoelastic component. The Bryan (Medtronic) and Advent (Orthofix) discs are metal-on-elastomer ball-and-socket articulating designs. The M6 (Spinal Kinetics) is a non-articulating, viscoelastic device but is not securely bonded (constrained).

It has been proposed that an elastomeric one-piece intervertebral prosthesis might be the most physiological implant for mimicking physiologic levels of shock absorption and flexural stiffness (36). Currently, only a few cervical TDRs fit this design description. The CAdisc-C (Rainier) is a graduated-modulus one-piece elastomeric device. The CP-ESP (FH Orthopedics) cervical disc consists of titanium plates securely fixed to a two-part urethane core. This disc has been implanted in Europe since 2012. One published study of 2-year follow-up of 62 patients at one or two levels reported good clinical outcomes and performance of the device (36).

The Freedom® Cervical Disc (FCD, AxioMed LLC), presented in this study, is a one-piece viscoelastic artificial disc consisting of an elastomeric core bonded to titanium alloy retaining plates which is intended to re-establish the function of the cervical spinal segment, augmenting the existing anatomical structures. Function is established by: establishing flexibility and natural resistance while creating stability within the functional spinal unit (FSU); providing viscoelasticity to mimic the dynamic stiffness and load sharing in the natural disc; preserving physiological range of motion (ROM) in flexion, extension, lateral bending, rotation, and compression; and, providing the correct spine alignment and lordosis. The objective of this study is to present clinical outcome data from a 2-year post-market study of the FCD in Europe.

Methods

Thirty-nine patients were enrolled by five study sites according to the criteria in *Table 1* between February 2013 and March 2014. Subjects received one- or two-level cervical TDR (FCD, AxioMed LLC, *Figure 1*) and underwent follow-up for two years. The study received local ethics approval for each study center, and all subjects gave written consent prior to study enrollment [Clinical trial registration No. NCT01763619 (clinicaltrials.gov)]. The ethics committees and approval information is included in *Table 2*.

Clinical outcomes included improvement of neck disability index (NDI) and visual analog scale (VAS) scores regarding the severity and frequency of neck and arm pain from baseline to 2-year follow-up, neurological examinations (manual muscle test, sensory and reflex assessments), the patient's view on the success of surgery, complications, and subsequent surgical interventions. The

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Skeletally mature males or females, aged 21 to 65 years old, inclusive
Single, or adjacent, 2-level degenerative disc disease at C3–C7, inclusive
Subject is a surgical candidate for an anterior approach to the cervical spine
Minimum of 6 weeks of unsuccessful conservative treatment. Subjects with progressive neurological deterioration may receive intervention prior to 6 weeks of conservative care if all other eligibility criteria are met
Subject with at least moderate preoperative pain and functional impairment as denoted by:
Neck disability index (NDI) score ≥40/100 points (40%–"moderate disability")
A VAS arm pain intensity score of ≥30 mm out of 100 mm in the right and/or left extremity
Subject is mentally and physically able to comply with protocol, postoperative compliance instructions, and follow-up schedule through 2 years
Subject must understand and sign the written Informed Consent form
Exclusion criteria
Subject with axial neck pain only who does not demonstrate concurrent arm pain or progressive neurological deterioration (specifically numbness or muscle weakness in the arm)
An active infection at the operative site or active systemic infection at the time of surgery
Known or suspected allergy to titanium, polyurethane, cobalt, chromium, molybdenum or silicone
Previous spinal fusion at the involved, or adjacent, cervical level(s)
Congenital or acquired structural defect at the operative levels (s) or their immediately adjacent level(s)
Significant osteoporosis in the cervical spine 1
Note that poor bone quality may be present if the subject has a DEXA T-score <–1.0 or a quantitative computed tomography (QCT densitometry) level <120 mg/cm^3
The investigator should assess if the subject has any of the following conditions at the index or adjacent level(s) which excludes the subject from study participation
Cervical facet degeneration of the involved C3–C7 levels
Previous trauma to, or fusion in, the C3–C7 levels
Cervical instability at the index level(s) on neutral lateral or flexion/extension X-rays; translation >3.5 mm and/or 11° of rotational difference compared to adjacent level(s)
Radiographic findings of a fused or total collapsed disc (central disc height ≤2 mm) or lack of motion (<2°) on flexion/extension X-rays
Significant global cervical kyphosis (≥15° on Cobb angle measurement) or significant reversal of lordosis

NDI was used according to the original publication by Vernon *et al.* (37). The score obtained was multiplied by two to produce a percentage score.

Implant and surgery

The FCD is a viscoelastic device intended to replace symptomatic degenerative cervical discs. The device functions by restoring the natural flexibility (motion) and stiffness (load carrying capacity) of the spinal system. This device re-establishes the local spinal segment, augmenting the existing anatomical structures (facets, muscles and ligaments) that make-up the FSU through its unique design and material make-up. The FCD is indicated for use only if conservative care (approximately 6 weeks of non-operative care) fails to reduce symptoms. The FCD is implanted via an anterior open procedure.

The device consists of an elastomeric polymer core, two

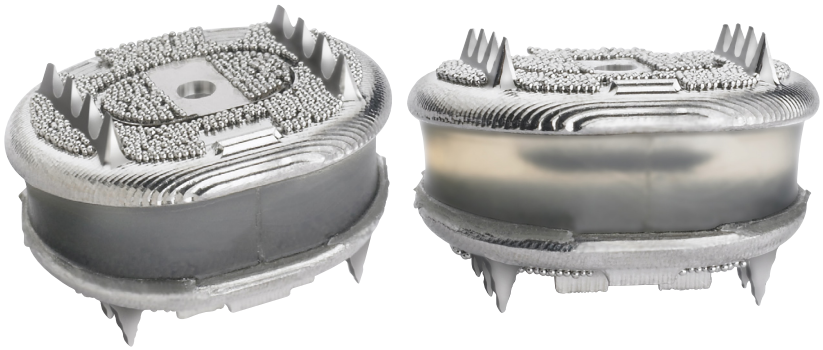

Figure 1 Freedom Cervical Disc.

Table 2 Clinical study sites

Clinical investigator and site information	Ethics committee information	Patients, n (%)
Burkhard Rischke, Spine Center Rischke, Zurich, Switzerland	Kantonale Ethikkommission Zurich; KEK-ZH-Nr. 2012-0514	1 (2.6)
Oliver Hausmann, Hirslanden Klinik St. Anna, Luzern, Switzerland	Kantonale Ethikkommission Zurich; EK: 13019	17 (43.6)
George Kiriyanthan, Stadtiches Klinikum Karlsruhe, Karlsruhe, Germany	Ethik-Kommission bei der; F-2013-022	3 (7.7)
Robert Pflugmacher, Universitatsklinikum Bonn, Bonn, Germany	Ethik-Kommission an der Medizinishen; AXMD230512POST	10 (25.6)
Marcus Eif, Klinikum Goerlitz; Girbigsdorfer, Goerlitz, Germany	Ethikkommission bei der Siichsischen; 23 b MPG	8 (20.5)

retaining plates, and one end cap that engages the superior retaining plate. The polymer core consists of a silicone polycarbonate urethane copolymer (trade name: CarboSil® TSPU) molded between two titanium alloy (ISO 5832-2, and ISO 5832-3) retaining plates which are porous bead coated. The device is offered in one wedge angle (8°), six sizes configured with three superior plate sizes ranging from 13 mm × 16 mm to 17 mm × 20 mm, three inferior plate sizes ranging from 12 mm × 15 mm to 16 mm × 19 mm and axial heights ranging from 5.7 to 6.9 mm. The FCD is supplied with surgical instrumentation which facilitates implantation.

Surgery was performed by a total of five surgeons in five centers. For detailed information on case distribution by center and surgeon see *Table 2*. Following a standard anterior approach and after total anterior discectomy and decompression the implant bed was prepared, and the implant size and height was tested by trial components. The preparation of implant rail slots into the caudal and cephalad vertebral bodies, as well as the implant's one-piece design, allows *en bloc* implantation, avoiding over-distraction.

Postoperative care was handled according to the center's standard procedures. The physical initial and follow-up examinations were done by either the investigators or other surgeons at the hospital.

Results

Patient demographics

A total of 39 patients from five locations in Germany and Switzerland were enrolled in the study (*Table 2*). The study population (*Table 3*) represents a similar distribution of male 20 (51%) and female 19 (49%) subjects with an average age of 45 years.

Intraoperative details and discharge

Thirty FCD were implanted at a single level between C3

Table 3 Patient demographics

Parameter	Summary
Subjects implanted	39
Mean age in years (range)	45 [25–61]
Number of females	19 (48.7%)
Number of males	20 (51.3%)
Mean BMI in kg/m^2 (range)	27 [19–49]
Smoking history	
Non-smoker	26 (66.7%)
<1 pack/day	9 (23.1%)
≥1 pack/day	4 (10.2%)
Employment status	
Employed full time	16 (41.0%)
Employed part time	6 (15.4%)
Self-employed	1 (2.6%)
Out of work/looking	1 (2.6%)
Out of work/not looking	2 (5.1%)
Student	0 (0.0%)
Retired	1 (2.6%)
Homemaker	3 (7.7%)
Unable to work/cervical spine	2 (5.1%)
Unable to work/other reasons	7 (17.9%)
Median pain	
Neck	9 [1–120]
Duration in months (range)	
Right arm	6 [1–72]
Left arm	5 [1–120]

Table 4 Intraoperative summary

Parameter	Summary
Subject implanted	39
Levels implanted	48
Index level(s)	
One level	30 (76.9%)
C3–C4	1
C4–C5	2
C5–C6	16
C6–C7	11
Two levels	9 (23.1%)
C3–C4–C5	0
C4–C5–C6	1
C5–C6–C7	8
Mean operating time: skin-to-skin in minutes (range)	
Overall	90 [45–210]
1 level	75 [45–155]
2 levels	90 [75–210]
Mean estimated blood loss in mL (range)	
Overall	50 [20–250]
1 level	50 [30–250]
2 levels	50 [20–100]
Mean length of hospital stay in days (range)	
Overall	5 [3–16]
1 level	5 [3–16]
2 levels	5 [3–8]

and C7, and nine [9] were implanted at two adjacent levels between C4 and C7 (*Table 4*). Based on surgical expertise, 50% of the surgeries was completed in 90 min, with an average blood loss of 50 mL, and operating time ranged from 45 to 210 min. For all patients in the study, intra-operative and post-op periods were uneventful, and no complications due to procedure or implant were observed.

Clinical outcome

No device related adverse events were identified by the principle investigators. Three [3] serious adverse events were related to the procedure. One, reported for retropharyngeal hematoma, was definitely procedure related. The remaining two serious adverse events, paresthesia of finger and dysphagia, were reported to be possibly related to the procedure. None of the procedure related adverse events were associated with malfunction of the surgical instruments. No reported adverse event was categorized as serious requiring vigilance reporting to local regulatory authorities. No devices were explanted during the study. X-rays illustrative of one- and two-level prostheses in flexion and extension are shown in *Figures 2* and *3*.

All patient self-administered clinical outcome measures showed continuous clinical significance from pre-operative evaluation and over the 2-year follow-up.

Preoperatively, 62% of participants had sensory deficit, 21% had reflex deficit, and 38% had motor function deficit.

These values improved tremendously to 32%, 11% and 16% for sensory, reflex and motor functions, respectively, by the time of discharge and continued to improve. At 2 years follow-up, sensory, reflex and motor function deficits persisted in only 17%, 6% and 3% of patients, respectively (*Tables 5-7*).

Post operation, 50% of the patients were discharged 5 days after the surgery. Significant improvement was observed immediately at discharge. Change in preoperative NDI and VAS mean scores demonstrated diminished disability and pain with improved functional status. Preoperative NDI improved from an average of 48% to 4% at 2 years (*Table 8* and *Figure 4*). Neck pain intensity decreased progressively from a preoperative value of 63 to 15 mm 2 years. Right and left arm pain intensity showed a similar decline in value, from 43 to 10 mm and 44 to 9 mm, respectively, during similar follow-up period (*Table 9* and *Figure 5*). Neck, right arm and left arm pain frequency declined steadily throughout the two-year follow up period (*Table 10*).

Patient satisfaction was high, with 83% of patients responding that they would "definitely" choose to have the same treatment for their neck/arm condition and another 11% responding that they would "probably" choose to have the same treatment. None of the patients responded that they would 'definitely not' have the same treatment.

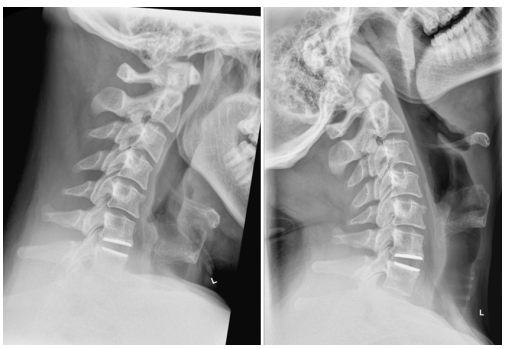

Figure 2 Lateral flexion and extension X-rays of TDR at C6/C7 at 2 years. TDR, total disc replacement.

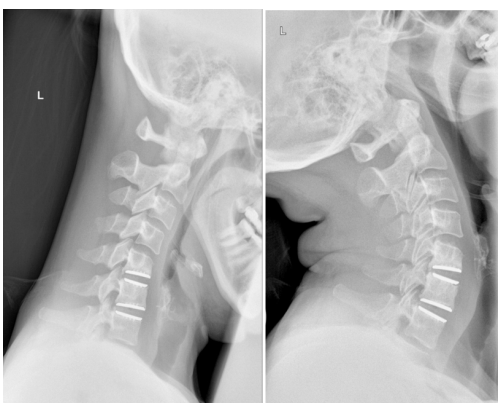

Figure 3 Lateral flexion and extension X-rays of TDRs at C5/C6 and C6/C7 at 1 year. TDR, total disc replacement.

Discussion

The FCD is one of very few TDRs with a viscoelastic, one-piece design that is intended to provide stability, flexibility, load sharing, natural resistance, alignment and lordosis. While it has been theorized that this design type will function most like the healthy intervertebral disc, it remains to be proven clinically. Will this type of design be the most successful at protecting the surrounding anatomy by providing stability and resisting excess motion? Will it slow the degenerative process because it restores proper alignment and lordosis? These questions remain to be answered by long term studies of one-piece viscoelastic TDRs.

In this study of one- and two-level implantation of a one-piece, viscoelastic TDR, all outcome measures showed significant, clinically important improvements from baseline to follow-up at 2 years. While all patients had sensory and/or motor deficits preoperatively, 77% of patients were asymptomatic at two years follow-up. Patient satisfaction

Table 5 Neurological evaluation—sensory function by interval

Sensory function	Pre-op	Discharge	6 weeks	3 months	6 months	1 year	2 years
N	39	38	38	37	38	33	35
Normal	14 (35.9%)	25 (65.8%)	32 (84.2%)	34 (91.9%)	32 (84.2%)	29 (87.9%)	28 (80.0%)
Abnormal	24 (61.5%)	12 (31.6%)	5 (13.2%)	3 (8.1%)	6 (15.8%)	4 (12.1%)	6 (17.1%)
NA	1 (2.6%)	1 (2.6%)	1 (2.6%)	0 (0%)	0 (0%)	0 (0%)	1 (2.9%)

Table 6 Neurological evaluation—reflex function by interval

Reflex function	Pre-op	Discharge	6 weeks	3 months	6 months	1 year	2 years
N	39	38	38	37	38	33	35
Normal	31 (79.5%)	33 (89.2%)	36 (94.7%)	35 (94.6%)	37 (97.4%)	32 (97.0%)	33 (94.3%)
Abnormal	8 (20.5%)	4 (10.8%)	1 (2.6%)	2 (5.4%)	1 (2.6%)	1 (3.0%)	2 (5.7%)
NA	0 (0%)	1 (2.6%)	1 (2.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 7 Neurological evaluation—motor function by interval

Motor function	Pre-op	Discharge	6 weeks	3 months	6 months	1 year	2 years
N	39	37	38	37	38	33	35
Normal	24 (61.5%)	31 (83.8%)	34 (89.5%)	35 (94.6%)	37 (97.4%)	32 (97.0%)	34 (97.1%)
Abnormal	15 (38.5%)	6 (16.2%)	3 (7.9%)	2 (5.4%)	1 (2.6%)	1 (3.0%)	1 (2.9%)
NA	0 (0%)	0 (0%)	1 (2.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 8 NDI scores

Disability	Pre-op	6 weeks	3 months	6 months	1 year	2 years
Number of patients	39	38	36	38	36	35
Mean % NDI (range)	48 [18–76]	20 (0–67)	12.5 (0–67)	8 (0–50)	6 (0–50)	4 (0–54)

NDI, neck disability index.

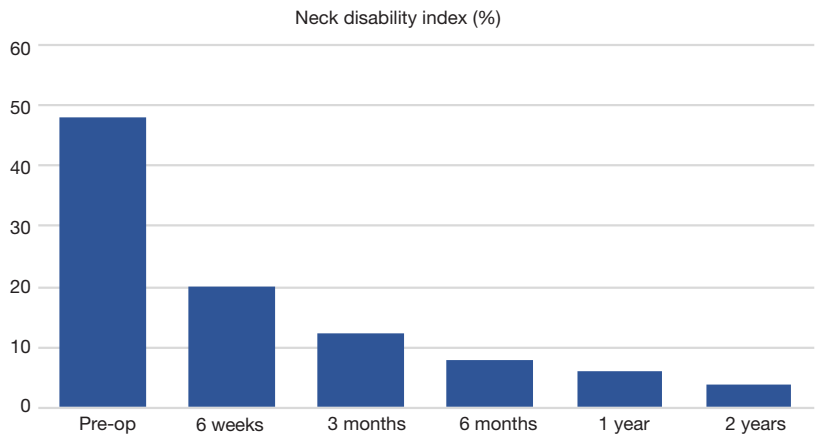

Figure 4 Neck disability index by interval.

was also very high.

FCD patients experienced improvements in neck and arm pain similar to those seen for both arthroplasty and fusion patients in randomized (4,6,8,9,13,38-40) and non-randomized studies (36,41-43). VAS neck pain for the FCD was reduced to 15 mm at 2 years compared to 24 and 38 mm for the M6 (41,42) in two different studies, and was reduced to 14 mm at 1 year compared to 26.5 mm for the CP ESP. The VAS neck pain of 15 mm reported in this study is similar to reported ranges of 13 to 27 mm for articulating discs including ProDisc-C, Mobi-C, Secure C, Discover, Bryan, activC, Kineflex C and Prestige, and 16 to 26 mm

Table 9 VAS intensity

Pain intensity	Pre-op	6 weeks	3 months	6 months	1 year	2 years
Number of patients	39	38	37	38	36	34
Mean VAS in mm (range)						
Neck	63 [2–200]	23 (0–87)	22 (0–76)	38 (0–70)	14 (0–60)	15 (0–90)
Left arm	44 (0–100)	11 (0–87)	10 (0–80)	8 (0–80)	6 (0–60)	9 (0–75)
Right arm	43 (0–100)	12 (0–94)	9 (0–63)	9 (0–65)	5 (0–50)	10 (0–90)

VAS, visual analog scale.

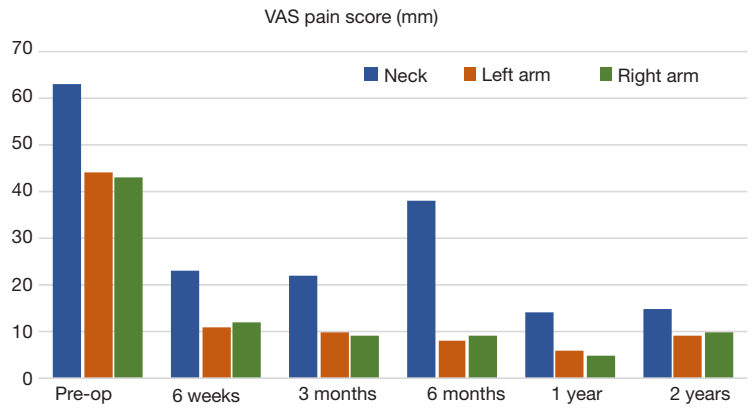

Figure 5 VAS pain intensity by interval. VAS, visual analog scale.

Table 10 VAS—frequency

Pain frequency	Pre-op	6 weeks	3 months	6 months	1 year	2 years
Number of patients	39	38	37	38	36	35
VAS in mm (range)						
Neck	80 [1–100]	38 (0–100)	32 (0–100)	26 (0–100)	19 (0–100)	15 (0–99)
Left arm	51 (0–100)	13 (0–100)	13 (0–60)	9 (0–50)	7 (0–60)	9 (0–98)
Right arm	52 (0–100)	16 (0–100)	12 (0–90)	9 (0–66)	7 (0–75)	10 (0–98)

VAS, visual analog scale.

for the fusion controls from the same studies (1,4,19,25, 38-40,43). VAS arm pain for the FCD was reduced to 9 mm (left) and 10 mm (right) at 2 years, compared to 21/16 mm (right/left) and 39 mm for the M6 (41,42), and was reduced to 7 mm at 1 year compared to 24 mm for the CP ESP. VAS arm pain of 9 and 10 mm at 2 years follow-up is similar to reported ranges of 7 to 14 mm for articulating discs and 8 to 19 mm for ACDF (1,19,25,38,43).

NDI for the FCD compared favorably to that for other TDRs and fusion. NDI was 4% at 2 years follow-up, compared to 20.8% (41) and 27.9% (42) for the M6 cervical disc in two studies. NDI at 2 years follow-up ranged from 12% to 40% for studies involving articulating discs (listed above), and from 17% to 38% in the fusion control groups for those studies (1,4,19,25,38-40,43). NDI was reported to be 24% for the CP ESP disc at 1 year follow-up (36), compared to an NDI of 6% for the FCD of at 1 year follow-up.

These results indicate that the technology is performing well for the follow-up period of 2 years. Additional studies

and long-term patient follow-up are still needed to assess long-term clinical outcomes of viscoelastic one-piece cervical TDR in general, and this technology in particular.

Conclusions

The FCD performs as expected in patients with single- and two-level degenerative disc disease. In this early clinical experience with the FCD, patients experienced similar pain relief and lower disability at 2 years follow-up compared to both articulating and viscoelastic TDRs.

Acknowledgements

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Footnote

Conflicts of Interest: The authors have no conflict of interest to declare.

Ethical statement: The study received local ethics approval for each study center, and all subjects gave written consent prior to study enrollment [Clinical trial registration No. NCT01763619 (clinicaltrials.gov)].

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