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Cervical TDR with up to 3 Years of Follow-up: The Mobi-C® French Study

T. Dufour¹, J. Beaurain², P. Bernard³, J. Huppert⁴, J.P. Steib⁵, J.M. Vital⁶, T. Vila⁷, I. Hovorka⁸, J.M. Fuentes⁹, P. Dam-Hieu¹⁰, J. Stecken¹

¹CHR Orleans, Neurosurgery, Orleans, France, ²CHU Dijon, Neurosurgery, Dijon, France, ³CAD, Orthopaedic Surgery, Pessac, France, ⁴Clinique du Parc, Neurosurgery, Saint Etienne, France, ⁵CHU Strasbourg, Spine Surgery, Strasbourg, France, ⁶CHU Pellegrin Tripode, Bordeaux, France, ⁷LDR Medical, Orthopaedic Surgery, Troyes, France, ⁸CHU Nice, Orthopaedic Surgery, Nice, France, ⁹Clinique du Millenaire, Neurosurgery, Montpellier, France, ¹⁰CHU Brest, Neurosurgery, Brest, France

The interest in cervical total disc replacement (TDR) as an alternative to the so-far gold standard in the surgical treatment of degenerative disc disease (DDD), e.g. anterior cervical discectomy and fusion (ACDF), is growing very rapidly. Many authors have established the fact that ACDF may result in progressive degeneration in adjacent segments. On the contrary, but still theoretically, preservation of motion with TDR at the surgically treated level may potentially reduce the occurrence of adjacent level degeneration (ALD). We report the intermediate results of an ongoing French multicentre prospective study of TDR with Mobi-C® prosthesis. Mobi-C® (LDR Medical, Troyes, France) was designed by a group of French orthopaedic and neurosurgeons with two main objectives: attempt to replicate the normal cervical intervertebral disc motion as much as possible and develop a device with well-known materials and wear profile which is easily placed with a simple and reliable technique. Mobi-C® was CE marked in 2004. The aim of the study was to assess the safety and efficacy of the device in the treatment of DDD and secondary to evaluate the radiological status of adjacent levels and the occurrence of ossifications, at each follow-up (FU). We did not exclude the learning curve cases of the study. For the 382 patients enrolled to date, the indications were DDD at one or more levels between C3 and T1, leading to radiculopathy and/or myelopathy. Surgery was performed only after failure of appropriate conservative medical treatment. A total of 532 prostheses have been implanted, 67% of the patients were operated with Mobi-C® at one level. Patients have been analyzed clinically and radiologically. Clinical outcomes (NDI, VAS, SF-36) and ROM measurements were analyzed preoperatively and at the different post-operative time-points. The study will be conducted for 10 years of FU. Complications and re-operations were also assessed. Occurrences of heterotopic ossifications (HO) and of adjacent disc degeneration radiographic changes have been analyzed. The mean NDI and VAS scores for arm and neck are reduced significantly at each post-operative time-point compared to pre-operative condition. Employment rate increased after the surgery compared with pre-operative situation. Motion is preserved over the time at index levels (mean ROM = 8.5° at 2 years) and 85.5% of the segments are mobile at 2 years. HO are responsible for the fusion of 27/158 levels at 3 years. However, presence of HO does not alter the clinical outcomes. The occurrence rate of radiological signs of ALD is very low at 2 years (9.5%). There has been no subsidence, no expulsion and no sub-luxation of the implant. Our preliminary results suggest the ability of arthroplasty with Mobi-C® to decrease the occurrence of ALD in surgical treatment of DDD. Actually there is a strong belief in the ability of this unconstrained device, thanks to its controlled-mobility core and self-positioning capacities, to enforce the possibility of adjacent levels preservation, but it must be confirmed by further long-term studies. Finally, after 3 years, 96% of the patients assume that they would undergo the procedure again. These intermediate results of TDR with Mobi-C® are very encouraging and confirm the efficacy and the safety of the device.