

# REVIEW

## Past, Present, and Future of Cervical Arthroplasty

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Cervical arthroplasty was developed in an attempt to maintain cervical motion and potentially to avoid or minimize adjacent-segment degeneration. If cervical arthroplasty is successful, the long-term results of surgery for cervical disc disease should improve. However, problems associated with cervical arthroplasty have been reported: these include kyphosis, heterotopic ossification-induced motion limitation, no motion preservation even at the index level, and a higher revision rate in a limited number of cases compared with anterior cervical discectomy and fusion (ACDF). In addition, for degenerative cervical disc disorders, the risk of developing adjacent segment degeneration more than 2 years after surgery is reportedly similar for ACDF and cervical arthroplasty. Cervical disc arthroplasty is an emerging motion-sparing technology and is currently undergoing evaluation in many countries as an alternative to arthrodesis for the treatment of cervical radiculopathy and myelopathy. The decision whether to use arthrodesis or arthroplasty is a difficult one. The achievement of good prosthetic performance demands exacting implantation techniques to ensure correct placement. This fact underlines the increasing importance of special instrumentation and surgical skills that involve an understanding of prosthetic lubrication, wear, and biologic effects and familiarity with currently available information regarding kinematics, basic science, testing, and early clinical results. Fortunately, a number of devices are at the late preclinical study stage or at the early clinical trial stage, and results in many cases are promising. In the near future, it is likely that new designs will be produced to replace spinal discs totally or partially in a pathologic entity-specific manner. (doi: 10.2302/kjm.2012-0014-RE) ; Keio J Med 62 (2) : 47–52, June 2013)

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### Introduction

For 30 years, anterior cervical discectomy and fusion (ACDF) has been a widely accepted intervention for patients with cervical radiculopathy or myelopathy unresponsive to conservative treatment. ACDF has been reported to provide excellent fusion rates and clinical outcomes;<sup>1–5</sup> however, it reduces the range of neck motion and increases adjacent segment degeneration (ASD) in the long term.<sup>6–8</sup> The past decade witnessed the emergence of cervical total disc replacement (TDR-C), in

which pathological discs are replaced with a mechanical device to preserve joint function.<sup>9</sup> Many types of TDR-C prostheses are at various stages of clinical trials, and several reports have documented their clinical efficacies.<sup>10–12</sup> TDR-C is advantageous for maintaining range of motion, preventing ASD, and promoting normal physiological curvatures.<sup>8,13–15</sup> It was initially suggested that TDR-C could reproduce normal kinematics after implantation, whereas cervical fusion alters spinal biomechanics and initiates or accelerates ASD.<sup>8,16,17</sup> However, a systemic review with disappointing results was published by Ce-

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poiou-Martin et al. in 2011,<sup>18</sup> in which 2 years of follow-up demonstrated that the effectiveness of TDR-C appeared to be similar to that of ACDF, and stated that there was only weak evidence that TDR-C may be superior to fusion for treating neck and arm pain. Bartels et al., in a meta-analysis, reported that the clinical benefits of TDR-C were not proven, and recommended that these costly devices not be used in daily clinical practice.<sup>19</sup> Thus, the situation regarding the clinical efficacy and safety of TDR-C is thoroughly confused. Accordingly, we reviewed newly reported TDR-C findings from several perspectives, including safety, long-term effectiveness, improvement of motion at the index level, adjacent segment degeneration, the recovery or maintenance of sagittal balance, the hybrid or multilevel technique, and the use of TDR-C in cervical spondylosis. In addition, we include a discussion on the future direction of TDR-C.

### Safety and Effectiveness after Long-term Follow-Up

As mentioned above, Cepoiu-Martin et al. and Bartels et al. reported disappointing results for TDR-C.<sup>18,19</sup> However, many articles endorse the merits of TDR-C. Garrido et al. performed a 48-month follow-up prospective, randomized, controlled, single-site, comparative study on the Bryan cervical disc and ACDF.<sup>20</sup> Favorable functional outcomes were demonstrated for TDR-C versus fusion, and the incidence of secondary surgery after TDR-C was lower than that after ACDF. Mummaneni et al. reported the results of a larger prospective, randomized, multicenter study in which the Prestige Cervical Disc System was compared with ACDF in patients treated for symptomatic single-level cervical degenerative disease.<sup>21</sup> The improvement in neck disability index score in the TDR-C group was greater than that in the ACDF control group. Furthermore, the TDR-C group also had a significantly lower rate of secondary surgery and supplementary fixation. In contrast, Murrey et al. compared the ProDisc-C total disc replacement device with ACDF and reported that clinical outcomes were equally improved after TDR-C and after fusion.<sup>22</sup> Reoperation, revision, and supplementary fixation rates within the first 24 months were also significantly lower after TDR-C than after ACDF. Quan et al. concluded that, 8 years postoperatively, TDR-C (Bryan cervical disc arthroplasty) maintains favorable clinical and radiological results, with preservation of movement and satisfactory clinical outcomes in the majority of cases,<sup>23</sup> whereas Yu et al. found that TDR-C is more effective than ACDF in terms of overall success and reoperation rates at 24 months in patients with single-level symptomatic cervical disc disease.<sup>24</sup> Long-term results have also shown that TDR-C tends to be more effective in some respects. Coric et al. showed comparable neural decompression and clinical results for TDR-C (Kineflex|C) and ACDF in a prospective, randomized study.<sup>25</sup> In that study, TDR-C was found to be associated with a sig-

nificantly higher overall success rate than fusion, while maintaining motion at the index level. These randomized controlled trials demonstrate that TDR-C is not inferior to fusion in terms of long-term safety or effectiveness.

### Improvement of Motion at the Index Level

TDR-C may offer other desirable improvements compared with ACDF, including preservation of motion, the potential to alter the natural history of cervical spondylosis, and the possibility of preventing accelerated degenerative change.<sup>26</sup> Many articles have demonstrated that TDR-C is associated with a significantly better index level range of motion (ROM) than ACDF in the long term. Auerbach et al. reported that TDR-C increases total cervical ROM more than ACDF does and maintains a physiologic distribution of ROM throughout the cervical spine 2 years postoperatively, which potentially lowers the risk of adjacent segment breakdown compared with the compensation for loss of motion at the operative level that occurs throughout the unfused cervical spine in ACDF.<sup>27</sup> In a study by Park et al., TDR-C was found to potentially restore and maintain lordotic alignment, disc height, and angular motion, while allowing translation at levels similar to those present before surgery.<sup>28</sup> In contrast, after ACDF, the superior adjacent level was found to develop increased angular motion compared with that observed preoperatively. Zhang et al. and Coric et al. also reported that TDR-C yielded good clinical results while maintaining ROM at the index level at 24 months after surgery.<sup>25,29</sup> Barrey et al. concluded that TDR-C generated better biomechanical conditions than ACDF did at adjacent levels; TDR-C limited the contributions of these segments to global ROM and reduced their internal stresses, but only partially restored native kinematics of the cervical spine.<sup>30</sup> In addition, Barrey et al.<sup>31</sup> in a 24-month follow-up found that radiological outcomes after TDR-C (Discocerv) did not fully restore native segmental kinematics and that it caused a significant reduction in flexion-extension and consistent cranial shifts of the centers of rotation. Furthermore, the *in vivo* biomechanical behavior of the prosthesis was found to be very close to that of good fusion, and lordosis was maintained at the operated level. Although the merits of TDR-C are somewhat controversial, it is clear that the technique is biomechanically and clinically effective in terms of preserving ROM at the index level.

### Adjacent Segment Degeneration

The principle rationale for cervical arthroplasty is to reduce the risk of the ASD that occurs after fusion.<sup>26</sup> ASD as a consequence of ACDF has been extensively reported,<sup>15,32,33</sup> but it has not been determined if such ASD is the result of the natural progression of degenerative disc disease, although it is recognized that fusion causes in-

creased stress at adjacent levels.<sup>6,34</sup> For this reason, TDR-C was proposed in an attempt to decrease the incidence of ASD via motion preservation at both index and adjacent segments.<sup>35–37</sup> Many reports show a reduction in the incidence of ASD after TDR-C, but these reports could be biased by the use of reoperation at an adjacent level to define ASD.<sup>18</sup> Surgeons are less likely to revise TDR-C, and patients are less likely to agree to surgery if it is believed that the device reduces the incidence of ASD. Thus, caution should be exercised when interpreting the data, even though the majority of studies report better outcomes regarding ASD after TDR-C than after ACDF. In a report by Garrido et al. on a prospective, randomized, controlled, single-site trial, ASD (defined by the requirement for adjacent level surgery) was lower in the TDR-C group (Bryan disc, 5%) than in the ACDF group (12%).<sup>20</sup> Furthermore, in a large prospective, randomized, multicenter study conducted by Mummaneni et al. in patients with symptomatic single-level cervical degenerative disease, the incidence of adjacent segment reoperation was significantly lower in the TDR-C group.<sup>21</sup> In a 12-month follow-up study by Park et al, adjacent-level angular motion was unchanged after TDR-C, but angular motion at the superior adjacent level increased after fusion.<sup>28</sup>

### Recovery or Maintenance of Sagittal Balance

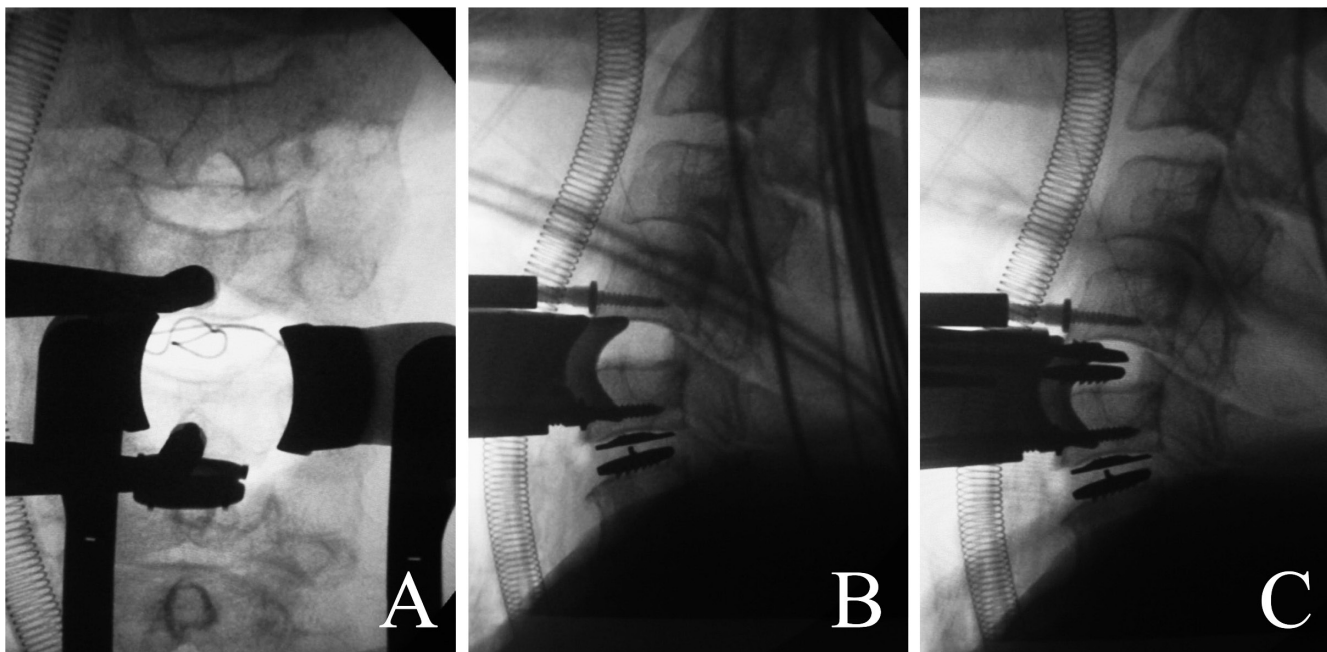
The relation between changes in spinal curvature and clinical outcomes is unclear. Nevertheless, kyphosis after TDR-C should be avoided to limit axial neck pain and stresses at adjacent levels.<sup>31</sup> TDR-C theoretically should offer motion preservation and the possibility of preventing accelerated degenerative change, and it could aid the maintenance of a natural spinal curvature. However, an earlier report showed increased sagittal kyphosis after TDR-C (Bryan),<sup>38,39</sup> which was probably caused by intraoperative lordotic distraction.<sup>38</sup> Functional spine unit angulation tends toward kyphosis, and in addition, height is reduced postoperatively because of insufficient anterior column support. Thus, these authors concluded that TDR-C should be carefully considered when the reconstruction or maintenance of cervical lordosis is desirable. After these studies were published, many authors reported that sagittal alignment recovered well in the long term, despite temporary kyphosis. Park et al. reported that cervical lordosis and thoracic kyphosis in their TDR-C group increased significantly more than in their ACDF group,<sup>8</sup> but Sasso et al. reported in a 2-year follow-up study with level I evidence that overall cervical sagittal alignment was no different in experimental and control populations.<sup>40</sup> Anakwenze et al. reported an increase in operated level (+3°) and C2–C6 lordosis (+3.1°) after TDR-C (ProDiscC) implantation in a level I evidence study involving 180 patients,<sup>30,41</sup> and, in a prospective study, consistently increased cervical lordosis after TDR-C (Disco-cerv) was also observed by Barrey et al.<sup>30</sup> Kyphosis could

occur after TDR-C as a result of too great a disc insertion angle and overmilling, and some authors have described techniques to help avoid these problems, such as changing the insertion angle<sup>42–45</sup> and depth.<sup>45</sup> Interestingly, in one of these reports, not one of 29 patients undergoing a modified TDR-C procedure (Bryan) developed kyphosis of the functional spine unit in the neutral position<sup>44</sup>.

### Hybrid Technique for Multilevel Surgery and TDR-C in Cervical Spondylosis

The hybrid technique involving arthrodesis and TDR-C has a biomechanical advantage over two-level fusion in terms of reducing adjacent level hypermobility. There has been some debate regarding the usefulness of the hybrid technique in patients that have previously undergone fusion or in patients with multi-level cervical disease or cervical spondylosis. *In vitro*<sup>30</sup> investigations and spinal structure models<sup>46</sup> have shown better biomechanical conditions at adjacent levels after TDR-C than after ACDF and that TDR-C limits contributions of these segments to global ROM and reduces the amount of internal stresses. Clinical reports by Lee et al. and Martin et al. also showed biomechanical advantages for the hybrid technique in terms of reducing adjacent-level hypermobility and increasing moment loads without causing impingement of the prosthesis end plate.<sup>47,48</sup> Several versions of the hybrid technique are available, as described by Cardoso et al.<sup>49</sup> Personally, I prefer the technique that uses TDR-C at the level of a well-preserved disc space, but ACDF in regions of larger motion. Multilevel cervical arthroplasty with TDR-C (Prestige ST) was reported by Cardoso et al. to be a safe and effective alternative to fusion for the management of cervical radiculopathy and myelopathy.<sup>50</sup> In that study, the technique for inserting TDR-C during contiguous multilevel cervical disc arthroplasty (which was presented as an alternative to multilevel arthrodesis) was described in 10 patients with radiculopathy and myelopathy; a similar technique was reported by Sekhon.<sup>51</sup> The hybrid technique with multilevel TDR-C was also reported with level II evidence by Huppert et al.<sup>52</sup> They found no major significant clinical differences between single- and multi-level TDR-C (Mobi-C).

Surgical indications for TDR-C were found to be extendable to cervical spondylosis,<sup>9,49–51</sup> defined as the presence of bridging osteophytes, loss of disc height of >50%, absence of motion (<2°), and a narrow spinal canal (<12 mm). However, some surgeons opposed to TDR-C in spondylosis have suggested that even TDR insertion could not be expected to achieve motion preservation when hard spurs or unciniate process-to-facet fusion is present.<sup>53,54</sup> Thus, others have recommended some techniques to overcome increased motion even in spondylosis, such as posterior longitudinal ligament resection with ventral foraminotomy<sup>53</sup> and/or bilateral unciniatectomy.<sup>54</sup>



**Fig. 1** Serial surgical procedure for cervical disc replacement with an artificial disc.

(A,B) The cartilaginous endplate was removed without damaging the bony end plate at the C4/5 level. (C) As part of the cervical arthroplasty procedure, an artificial disc (Mobi-C; LDR Medical, Troyes, France) was inserted. This disc prosthesis is a three-piece, bi-articulating, metal-on-polyethylene, semiconstrained device that consists of two metal base plates with an ultra-high molecular weight polyethylene insert. This insert is claimed by the manufacturer to be based on a mobile-bearing technology that improves ROM. Two lateral stops on the inferior endplate limit movement of the insert.

### Future Perspectives

Many questions about TDR-C remain unanswered,<sup>26</sup> such as those concerning debris produced by devices, subsidence, and the long-term rate of adjacent segment degeneration after disc replacement. Arthroplasty seems to be as safe as ACDF, which justifies its use in the short term, but it may become a substitute for fusion in the future.<sup>26</sup> However, the question as to whether TDR-C reduces the incidence of adjacent segment degeneration remains unanswered. Nevertheless, it would seem reasonable to continue with disc replacements in selected patients to determine long-term results and indications. There is no role for the indiscriminate use of arthroplasty, which should not be considered simply as a successor or replacement for fusion. Quality of life and cost effectiveness also need to be assessed in the long term, especially given the pressures caused by increasing costs that affect every healthcare system today. Solid long-term data are needed before we can fully appraise the role of arthroplasty, and we therefore need to ensure that the momentum to follow-up this group of patients is maintained. In fact, the present standard of treatment may be flawed, but we will only really know where arthroplasty stands if the spirit of research is sustained.<sup>26</sup>

### Surgical Steps of TDR-C Using the Mobi-C Prosthesis

A standard Smith-Robinson approach was used to expose the treatment levels. The cartilaginous end plate was removed with a curette taking care not to damage the bony end plate. The uncovertebral joints were left intact. An artificial disc (Mobi-C; LDR Medical, Troyes, France) was used for cervical arthroplasty (**Fig. 1**). This disc prosthesis is a three-piece, biarticulating, metal-on-polyethylene, semiconstrained device consisting of two metal base plates with an ultra-high molecular weight polyethylene insert. Two lateral stops on the inferior end plate limit movement of the insert. This artificial disc has received approval from the Food and Drug Administration to undergo an investigational device exemption trial in the United States.

### Conclusions

This study reviews recent articles on TDR-C and presents multiple perspectives. The long-term safety, effectiveness, and preservation of motion at the index level of TDR-C are well supported by evidence, but the recovery and maintenance of sagittal balance are similar to those

for conventional fusion. Although sufficient evidence is not yet available, the hybrid multilevel technique and the broad application to cervical spondylosis are also possible. There is no reason to be hesitant about considering the use of TDR-C.

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