Biomechanical Comparison of A Novel Dynamic Cervical Implant With Conventional Implant: A Finite Element Study

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Abstract. Ball-socket pair is generally used for designing implants for total disk replacement (TDR) surgery on cervical spine. Although, there exists an issue of wear which reduces implant’s life as well as success rate. To overcome this issue, without compromising stability, a new design of dynamic cervical implant (DCI) is introduced. In this present study, biomechanical performances of a conventional Prodisc-C and the proposed DCI were compared using finite element (FE) analysis. CT scan data was used to develop three-dimensional model of cervical spine (C4–C7), and the implants were inserted at C5-C6 segment. The FE model with Prodisc-C showed an increase in range of motion (ROM) at the implanted segment and decrease in adjacent segment, while the proposed DCI design showed convenient results in term of ROM compared to intact spine model, and lower risk of stress shielding at the adjacent bone.

Keywords: Finite Element Analysis, Total Disc Replacement, Range of Motion.

1. Introduction

Spinal fusion is being used as surgical intervention for degenerative discs for last few decades [Jain et al., 2020]. However fusion surgery involves risk of further degeneration and increased disc pressure at the adjacent segments. To overcome this, total disc replacement (TDR) is gaining popularity as an alternative to fusion surgery. There are different commercially available TDR such as Prodisc-C, Charité, Prestige LP, Bryan etc [1,2]. Most of the TDR devices are designed as ball and socket pair consisting a soft-core articulating between two rigid endplates, which allows motion between the connected vertebrae. TDR has showed a remarkable callability to restore motion the in the spine segments affected due to degenerative diseases [3, 4]. Although some recent biomechanical studies claimed TDR cause hypermobility in the operated segments due to low coefficient of friction in the ball socket pair [5]. This hypermobility may lead to increase facet joint force and strain in the ligaments. Additional to this this problem, in TDR there as a potential risk of spreading wear debris caused by sliding of the contact pair, which may cause osteolysis leading to bone loss and loosening of the implant. The wear debris may also cause tissue necrosis in the periprosthetic tissues. Recently some dynamic stabilization devices are introduced to avoid the problems caused by the ball socket contact pair [6]. Dynesys device is showed a good stability at the operated segment, but it is also reported that this device cannot be used where limited flexibility is required [7]. Preliminary study on flexible spinal stabilization device proposed by Biswas et al., [8] showed favourable outcome and optimum implant dimension [24, 25]. FlexPlus device is reported to preserve 50% motion of that of intact spine segment [9]. So, there is a continuous need to improve the performance of available surgical devices for treating degenerative disc related diseases.
In this study, the biomechanical performance of a U-shaped dynamic device is analysed. The device is inserted at the C5-C6 segment of a three-dimensional (3D) spine model (C4-C7), and performance of the device is compared with Prodisc-C, using finite element (FE) analysis.

2. Materials and methods
The 3D geometry of the C4-C7 spine segment was constructed by using Computer Tomography (CT) scan data of healthy female subject (55 years old, 150 cm weight). The CT slices are imported into image processing software MIMICS to develop the 3D model of C4 to C7 vertebrae (figure 1) [10, 11]. Geometry of the discs (between the vertebrae) consisting nucleus pulposus and annulus fibrosus were modelled manually.

Figure 1: Development of spine model from CT scan data.

The dynamic cervical implant (DCI) consists of two 1.5 mm thick endplates and semi-circular arc with inner radius of 3 mm and outer radius of 5.5 mm (figure 2). The DCI was fixed with C5 and C6 vertebrae using bolts (figure 3). The dimensions of Prodisc-C consisting two endplates and ball-socket type sliding contact pair were adopted from the available literature [12].
The implanted spine models as well as intact model were exported to finite element package ANSYS (2019 R2). The vertebrae, discs and implants were discretised using quadratic tetrahedral elements and ligaments were meshed with link element [13]. The mechanical properties (density, \( \rho \) and elastic modulus, \( E \)) were calculated element wise based on Hounsfield Unit (HU) of the CT scan from MIMICS, and poisons ratio (\( \mu \)) was considered as 0.3 [14]. The mechanical properties of the ligaments were taken from literature [15], and that of discs are as follow: for Nucleus Pulposus \( E = 1 \text{ MPa, } \mu = 0.49 \), and for Annulus Fibrosus \( E = 3.4 \text{ MPa, } \mu = 0.4 \) [16]. The DCI is made of stainless steel \( (E = 195 \text{ GPa, } \mu = 0.29) \) [17]. The metallic endplates and the polymer core of the Prodisc-C were considered as Co-Cr-Mo \( (E = 290 \text{ GPa, } \mu = 0.29) \) and UHMWPE \( (E = 690 \text{ MPa, } \mu = 0.45) \) [17]. Coefficient of friction in sliding contact pair of Prodisc-C was 0.05, rest of the contacting interfaces were considered as bonded. A vertical compressive force of 50 N was applied at the superior surface of C4 vertebra and 1 Nm moment was applied in flexion-extension and lateral bending. The inferior surface of the C7 vertebra was constrained in all directions.

### 3. Results

Range of motion (ROM) of three motion segments i.e., C4-C5, C5-C6 and C6-C7 of three models (two implant models and intact model) were measured by the method described by Biswas et al. [18, 19] and compared under flexion-extension and lateral bending strain in peri-implant bone and stress on the implants were measured.
ROM of the intact model in C4-C5, C5-C6 and C6-C7 segments were 10.5°, 12° and 9.5° in flexion extension and 4°, 4.6° and 3.8° in lateral bending. In case of Prodisc-C implant, an increase in ROM was observed in the implanted segment. ROM in C4-C5, C5-C6 and C6-C7 segments were 10.6°, 15° and 9° in flexion-extension and 4.2°, 5.4° and 3.7° in lateral bending. Whereas in the DCI implanted model ROM were 10.8°, 11.3° and 9.7° in flexion-extension and 4.25°, 4.3° and 4° in lateral bending in the C4-C5, C5-C6 and C6-C7 segments respectively.

Stresses developed in the implants were within safe zone. Maximum von Mises stress developed in the DCI under extension was 185 MPa, which is much lower than the yield strength of SS. In case of Prodisc-C, maximum von Mises stress on the metallic endplate was 210 MPa, was also lower than the yield strength of Co-Cr-Mo.

Strain generated in the peri-implant bones play an important role in bone regeneration. In case of Prodisc-C, average strain in the inferior surface of C5 (bone-implant interface) was within a range of 275-292 microstrain and in the superior surface of C6 was 285-312 microstrain. Whereas, in DCI average strain were within a range of 305-316 and 322-336 microstrain in the inferior surface of C5 and superior surface of C6 respectively.

4. Discussions

In this study, biomechanical performance of the DCI is evaluated and compared with commercially available Prodisc-C. ROM of the intact model under flexion-extension fall within the standard deviation of results of previously published experimental studies [20, 21]. It was observed that ROM at the implanted segment is increased by 25% in flexion-extension and 17% in lateral bending compared to intact segment while using Prodisc-C. While ROM in the adjacent segments are change in the range of ±5%. Whereas using the DCI, ROM in the implanted segment was decreased by 5.8% under flexion-extension and 6.5% under lateral bending. In the adjacent segments, ROM changed within a range of 2.1-6.25%. This indicates that the DCI maintained closer ROM compared to intact spine with a variation of -6.5 to 6.25% against the variation of -25 to 5% in case of Prodisc-C. The hyper mobility in the implanted segment is caused due to the low friction coefficient between the ball socket sliding pair. The hyper mobility caused by Prodisc-C may introduce excess tension in the ligaments, creating instability in the entire segment. Some previous studies also reported hyper mobility caused by TDR. Tang et al. [22] observed around 25% increase in ROM in the implanted segment for using Prodisc-C. Similar results were also reported by Lee et al. [23], where hyper
mobility as 19% in flexion, 48% in extension and 28% in lateral bending. However, results of this primary study indicate that this problem may be avoided by using the proposed DCI. The stresses developed on the implants are much lower than the yield strength of the implant materials. Although, fatigue analysis is necessary to perform before in vivo or clinical trial. Strain developed in the peri-implant bone were higher for both the implants than the intact spine mode, which ensures reduced risk of stress shielding. However, average generated by the DCI was higher than Prodisc-C. This indicated overall better performance of the DCI. Few limitations were still there in this study, firstly CT scan data of only one healthy subject was considered in this study, which may not be appropriate for the generalisation of this problem. Secondly, simplified linear mechanical properties of the intervertebral discs were considered to reduce computation time. Thirdly, dynamic loading and fatigue analysis were not performed in this study.

5. Conclusion
Form the results, it may be concluded that due to low friction coefficient, the TDR implant, Prodisc-C may lead to hyper mobility in the implanted segment, due to which stability of the segment may be compromised. The proposed DCI may maintain the mobility of the spine. It was also revealed that the DCI generate favourable strain in the peri-implant bones. More studies be carried out using improved model and dimensions of the DCI to achieve better performance.

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