

M6^C
artificial cervical disc

October, 2010



M6-C Preserves Index Level and Adjacent Level Centers of Rotation

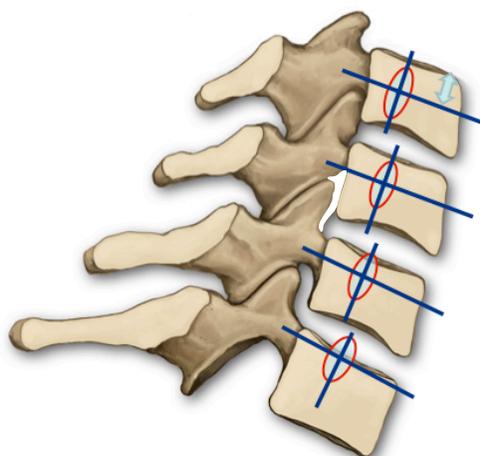
The Center of Rotation (COR) is described as the point about which the superior vertebra rotates relative to the inferior vertebra. In the cervical spine the COR is located in slightly different locations on both the X and Y axis in each different vertebral level. As you can see in the “Normal COR” illustration below, the location of the “normal” COR moves more anterior (X axis) and more cranial (Y axis) moving down from C2 to C7.

The COR also moves within each disc space as the spine goes thru the complex coupled motions of normal activities.

These COR changes that occur within a particular segment are known as the “Instantaneous Axis (or Center) of Rotation” (IAR). The range of IAR’s in a particular disc level are known as “centrodes” and are represented as you see in the illustration. As you might expect, these variables place quite a demand on any device that tries to replicate the normal motions of the spine. Because of the the design of the M6-C, the nucleus is able to likewise adapt to the IAR. We have seen evidence in the studies done by Dr. Patwardhan how well the intact COR is preserved and matched by M6-C following insertion, as well as how the adjacent

level COR is maintained with M6-C. At our recent Workshop at Eurospine 2010 in Vienna, Medical Metrics presented data on follow up patient X-rays that likewise show this same preservation of index level and adjacent level COR following M6-C implantation. Medical Metrics is the industry standard analysis lab for virtually all cervical and lumbar disc prosthesis. Surgeons who have read papers on any of the discs studied in the US will be familiar with Medical Metrics and their work.

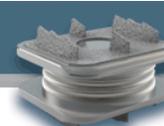
“Normal” Center of Rotation



■ Normal COR

Mean + 95% Confidence Interval (Hipp & Wharton, 2008)

COR is level-dependent
Posterior to mid-line



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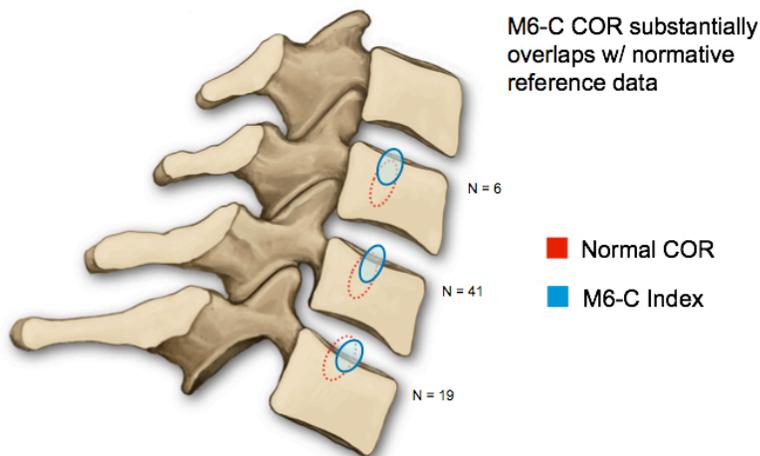


In complete agreement with the studies done by Dr. Patwardhan, an X-ray analysis by Medical Metrics of our US Pilot Study and German Registry patients at 12 months show that the COR at the index levels of each M6-C “substantially” overlapped the known areas of COR for every treatment level. These patients were both single and double levels. What this means is that the M6-C adapts to the COR that is normal for any particular disc space and vertebral level. Also, these patients were operated on by many different surgeons, with the location of the M6-C implant within the disc space naturally varied from surgeon to surgeon and patient to patient, so these results are based on “real life” clinical situations, not controlled lab experiments. The illustration to the right graphically shows the tabulated results, with the number of discs implanted at any given level.

For preservation of the COR of the levels adjacent to M6-C implantation, the X-ray analysis showed that the CORs were preserved and overlapped the normative CORs “perfectly”. This is very compelling evidence that when the M6-C is implanted, not only are the biomechanics of the index level maintained and COR matched, but the rest of the spinal COR remains unaltered. Remember that this study is done in single and double level patients, which again validates that M6-C is able to adapt to the COR of any level and maintain both the index and adjacent level biomechanics. The illustration to the right clearly shows how perfectly the adjacent level CORs are maintained.

This study, along with the strong experimental data provided by Dr. Patwardhan, is great ammunition for you in discussion of the properties of the M6-C and it’s ability to mimic the native healthy disc and functional spinal unit’s biomechanics and kinematics.

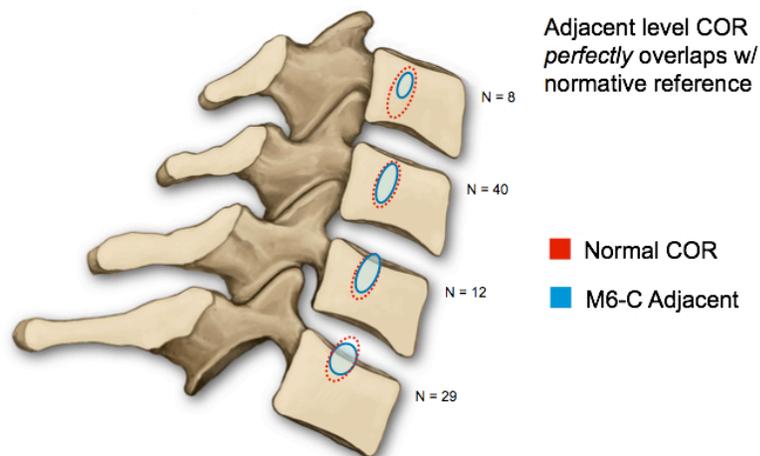
M6-C Center of Rotation (Index Level)



US & German data pooled; 1- & 2-level data pooled; 12-month results



M6-C Center of Rotation (Adj. Level)



US & German data pooled; 1- & 2-level data pooled; 12-month results

