Coflex

Interspinous device

Results

The results of this first prospective controlled study indicate that the additional placement of a Coflex™ interspinous device does not improve the already good clinical outcome after decompressive surgery for LSS in the 24-month follow up interval [1)].

After microsurgical decompression, Coflex™ device was applied. Patients were evaluated at a month after surgery and last follow-up using the visual analogue scale (VAS) and Oswestry Disability Index (ODI). Foraminal height and lumbar lordosis angle were recorded.

The mean preoperative VAS was 7.85 and fell to 1.7 a month after surgery ($p < 0.0001$). At the last follow-up the mean VAS score was 1.65 ($p < 0.0001$). The mean foraminal heights were measured 19.95 mm preoperatively and 25.05 mm a month after surgery ($p < 0.0001$). The mean foraminal height was 21.60 mm at the last follow-up ($p=0.002$). The mean lumbar lordosis were measured 32.05 and 34.3 degrees at preoperative and a month after surgery respectively ($p=0.155$). The mean lumbar lordosis was 32 (±5.99) degrees at the last follow-up ($p=0.974$).

Restoration of the foraminal height may not be a responsible factor for clinical improvement. Microsurgical decompression looks responsible of the good clinical outcome and using interspinous device is unnecessary. Comparative clinical studies can be informative [2)].

So far, inconsistent results in currently available retrospective studies. Comparable short-term results in prospective studies of sole decompression without implantation of an interspinous spacer. Prospective randomized comparative studies are not yet available [3)].

Complications

A high incidence of heterotopic ossification (HO) has been detected after implantation of Coflex devices. Clinicians should be aware of this possible outcome, and more studies should be conducted to clarify the clinical effects of HO. [4)].

Coflex implants should be avoided in patients with osteoporosis, a narrow interspinous space and intervertebral coronal spondylolysis, or sagittal instability. Furthermore the device choice, depth of implantation, and clamping intensity should be appropriate. Conservative treatment can be provided to patients with symptoms if the device remains in the correct position; however, revisions and salvages should be undertaken with internal fixation of pedicle screws for patients with device malposition, intraoperative implantation failure, or device intolerance [5)].

1)
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