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Interspinous Distraction Devices, has this Lost its Place in Treatment Algorithm?

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Opinion

Degenerative lumbar spinal stenosis leading to neurogenic claudication is a common cause of lower back and leg pain. It is generally caused by degeneration of the lumbar vertebrae and their associated joints causing compression of the spinal nerves. It presents significant health issues, causing a reduction in quality of life and large societal health care costs. The traditional treatment for those that do not respond to conservative measures is surgical decompression with or without fixation. Simple interventions such as epidural steroids are not recommended by National Institute for care and excellence (NICE). This is a major invasive surgical procedure carrying significant peri-operative risks. Interspinous distraction devices were developed to offer a minimally invasive alternative which can be performed percutaneously with fluoroscopic guidance under local or general anaesthesia. Their mechanism of action is reported to be decompression of the spinal nerves by increasing the interspinous distance and stabilisation of the spine [1]. The first interspinous implant was described by Knowles in the 1950s but was abandoned due to design flaws. Further development restarted in the 1980s and by the mid 2000's several devices were commercially available including X-Stop, Coflex, DIAM, Wallis, BacJac, Viking, Ellipse and Aperius [2].

The hypothesised benefits of these devices were reduced pain, improved function and reduced perioperative complications, especially in frail elderly population groups. The initial studies showed promising results with improvement in function compared to conservative measures [3]. These positive results led to a significant increase in use of these devices for degenerative spinal stenosis and other associated conditions. In 2010 NICE issued UK guidance supporting the use of interspinous distraction techniques in carefully selected patient groups with degenerative spinal stenosis [4]. Following this guidance several multi centre studies have been published looking at the longer-term results. These studies demonstrate less favourable long-term results with high failure rates and frequent requirement for more difficult revision surgery compared to primary surgical decompression. The reasons for the failure of the device are generally due to malposition, either secondary to dislocation due to supraspinous ligament rupture or spinous process fracture caused by a combination of excess distraction and osteoporotic bone [5,6].

The Minuteman is a minimally invasive, interlaminar fusion device intended for the temporary fixation of the thoracic, lumbar and sacral spine while awaiting bony fusion to occur. The advantage of this device is its ability to form bony fusion providing longer term success in distraction and decompression. A Multi-Centre Randomised controlled study was set up in 2012, Efficacy and Quality of Life Following Treatment of Lumbar Spinal Stenosis, Spondylolisthesis or Degenerative Disc Disease with the Minuteman™ Interspinous Interlaminar Fusion Implant versus Surgical Decompression: A Prospective Randomised Trial [7]. The study started enrolling in 2012 at 3 centres and increased to 4 centres in 2017. One of the centres had the Principal Investigator retire and no one to take over the study. We have screened more than 500 patients and recruited 44 patients over the last 6 years. The common cause for recruitment failure was either too low a stenosis (L5S1), where this device can't be placed or too tight a stenosis.

Minuteman is another form of Interspinous device and the UK surgical experience in these devices has been variable. Even though this has potential advantages in forming a fusion between Interspinous process making it longer lasting therapy, the general uptake from the neuro and spinal surgeons was not positive. This was reflected in the ability to recruit to this study in a timely manner. With increasing pressure on the NHS, less complex cases such as micro discectomy, foraminotomy and laminectomy were moved to the private sector for capacity and simple decompressions formed a majority, making recruitment difficult. Our first cohort of patients

has been followed-up for 5 years and we have shown a similar outcome to surgical decompression in our interim analysis with no explants due to lack of efficacy or failure. This we believe is due to the new bone formation making the interspinous distraction more permanent.

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