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Chapter 1

General Introduction
Intermittent neurogenic claudication (INC) is a complex of symptoms caused by degenerative lumbar spinal stenosis (LSS). The disease was first described by Van Gelderen in 1948 and Verbiest in 1950. The characteristic symptoms are leg pain (frequently both legs), which can be exacerbated with prolonged walking and standing and/or lumbar extension, and associated back pain. As in other acquired diseases, INC is usually seen in the elderly. Severe stenosis is common in elderly spine: 30.4% in the population have a severe stenosis (average age 67.3). However, only 17.5% of them have typical INC symptoms.

Diagnosis and imaging techniques:
The explanation of the symptoms is often disputed: Verbiest et al stated that the narrowing of the canal (due to degenerative tissue) leads to compression of the nerves and therefore causes symptoms of nerve impairment. Measuring the diameter of the lumbar spinal canal was the main tool to diagnose LSS and subsequently INC. Verbiest started in the 1950s with in vivo measuring techniques. In the 1960s Evans described a complete cerebral spinal fluid stop, on myelography, at the lower lumbar levels in patients with intermittent neurogenic claudication. Imaging techniques were used, after that discovery, preoperatively to select patients for surgical treatment. First myelography was used to prove a complete spinal fluid stop and later Computer Tomography images were used. Nowadays Magnetic Resonance (MR) imaging techniques are used to select patients with INC for treatment. Many different grading scales (such as the Schizas scale) exist to differentiate between mild and severe lumbar spinal stenosis on MR images. Nevertheless, good prospective studies have not been performed to assess the effectiveness and quality of MR imaging techniques and stenosis grading scales.

Surgical treatment:
Surgical treatment is considered to be the gold standard for patients with INC caused by LSS. However, the first prospective comparative study proving that surgical therapy was superior in comparison to conservative treatment was published in 2007. The first technique that was described to widen the lumbar spinal canal was wide bony decompression (laminectomy). Until today this technique is widely used. However since, INC is often accompanied by back pain, and thus to postoperative back-pain, it is hypothesized that a wide decompression is a ground for potential instability. Therefore, less invasive techniques, such as laminotomy (partial removal of the lamina), were developed and implemented.
Nevertheless, long-term clinical results after surgery are quite poor: only 64% of the patients are satisfied after surgical treatment. Numerous patients still complain about back pain after surgery. In order to solve this ‘problem’, a French group introduced a new, non-rigid fixation for patients with LSS and associated back pain in 1984: the Wallis system. It was a new idea to implant non-rigid implants to indirectly decompress the lumbar canal and to ‘unload’ the facet joints. The idea was based on their experience of implanting non-rigid implants in other joints. The Wallis system was first implanted in 1986. Nowadays, (other) interspinous process devices (IPDs) are used in the treatment for LSS and also others for back pain. The X-stop and Coflex implants were first used in the USA in an FDA trial. In contrast, in the European countries surgeons started to implant these devices right away (not in any prospective study design). As a result, these implants are widely used for almost 30 years to treat patients with INC caused by LSS.

Objective and outline of this thesis
The main objective of this thesis is to compare bony decompression with implantation of interspinous process devices (IPDs) in patients with intermittent neurogenic claudication (INC) caused by lumbar spinal stenosis (LSS). At the start of this research project, no double blind randomized study on this subject was published. However, implantation of IPDs was already part of the daily practice in some Dutch neurosurgical and orthopedic clinics. In chapter 2 a national survey among Dutch spine surgeons is presented about the usual care of patients with intermittent neurogenic claudication caused by lumbar spinal stenosis. Surgeons’ expectations of different treatment options are presented. The existing evidence on interspinous implant surgery will be systematically reviewed in chapter 3. Results of treatment with IPDs are compared with other (conservative) treatment options. In chapter 4 the design of the Foraminal Enlargement Lumbar Interspinous distraXion (FELIX) trial is described. This double-blind, multicenter, randomized (cost)effectiveness study was designed to answer the question whether treatment with IPDs would be more (cost) effective compared with conventional bony decompression. Short-term results (eight weeks), long-term results (one year) and results in different subgroups are described in chapter 5. The two-year results are presented in chapter 6. The analysis based on total direct and indirect costs of both procedures (treatment with IPD and bony decompression) are presented in chapter 7.
Measuring the amount of lumbar stenosis via estimating the compression on lumbar magnetic resonance imaging is now considered standard in the preoperative work-up in patients with INC suitable for surgical treatment. However, correlation between baseline clinical complaints and the compression on MR images has never been evaluated. Furthermore, the prognostic value of compression on MR images at baseline for the extent of possible recovery at long-term clinical follow-up is also not known. Results of the degree of compression on MR images compared with clinical functioning at baseline and long-term follow-up are presented in chapter 8.

Without any good prognostic evidence, new devices have been implanted to treat patients with INC. Drugs are introduced using robust introduction models. However, it is possible to use spinal implants in patients without any good clinical evidence. Ethical considerations of the introduction of these devices are presented in chapter 9.

Summary and conclusions are presented in chapter 10 in English and in chapter 11 in Dutch.
Reference List