Available online at www.sciencedirect.com

ScienceDirect

Procedia CIRP 65 (2017) 273 – 278

www.elsevier.com/locate/procedia

3rd CIRP Conference on BioManufacturing

Optimizing the architecture of a dynamic spinal implant for customized mechanical behavior

Yann Ledoux [a], Antonio Ramos [b], Michel Mesnard [a, *]

[a] *Université de Bordeaux, Institut de Mécanique et d'Ingénierie, CNRS UMR 5295, 33405 Talence, France*
[b] *University of Aveiro, Department of Mechanical Engineering, 3810-193 Aveiro, Portugal*

* Corresponding author. *Tel.:* +33-607-688-092. *E-mail address:* michel.mesnard@u-bordeaux.fr

Abstract

Non-fusion technology in spine surgery reduces surgical morbidity and degeneration of the adjacent levels by the insertion of dynamic spinal implants. Despite these advantages, a dynamic spinal implant (DSI) generates complications which require clinical follow-up, the continuous development of constructive solutions and structured optimization of the implant architecture using current mechanical design methods.

This study structures this optimization process of a DSI concept by incorporating the mechanical behavior of the device, design variables and functional requirements into a global design model. The geometric (descriptive anatomy) and mechanical (materials, components, etc.) characteristics are obtained from a literature review. By combining these parameters, variables and requirements, appropriate values can be determined. The resulting mathematical model is then used to design and implement a device that is suitably adapted in movements and stiffness. The model assumes linear or non-linear behavior.

We describe the optimization of the design variables to ensure the correct functioning of the mechanism when adapted to the patient. The optimization purpose is to determine the architecture of the implant, the choice of materials and the geometric parameters of implantation. An optimized implant model corresponding to specific degrees of degeneration in the intervertebral joint can then be envisaged.

Peer-review under responsibility of the scientific committee of the 3rd CIRP Conference on BioManufacturing 2017

Keywords: Dynamic implant; Design; Mechanical Model; Optimization.

1. Introduction

More than 5% of the world's population suffers acute back pain, especially as a result of degenerative pathologies of intervertebral discs. This degeneration leads to deterioration in the disc properties (loss of shock absorption, collapse, disc herniation, etc.).

The lumbar spinal segments are highly stressed and particularly badly affected during movement and when carrying loads. Disabling pain (lumbago) is usually accompanied by nerve pain (sciatica, cruralgia) which can generate a risk of paralysis.

The initial treatment of disc degeneration is to apply conservation options (drugs, rehabilitation, etc.); 5% to 10% of patients find no relief. Implant surgery is then the second treatment option to improve quality of life.

The fusion technique is often used in spine surgery and is the benchmark treatment. Posterior instrumentation (pedicle screws and rods) results in the complete and definitive suppression of mobility in the operated segment. Although the clinical results may be satisfactory, this technique can have some highly negative consequences: accelerated degeneration of the adjacent vertebral levels, screw loosening, etc. [1].

As a result, more recently, "non-fusion" systems have gradually been developed. The aim of these dynamic spinal implants (DSI) is to limit the evolution of the pathology, to preserve partial mobility and to reduce intradiscal pressure. Kaner proposes a classification of these DSIs into two groups: anterior devices and posterior devices [2].

Anterior devices include total disc prostheses and nucleus pulposus prostheses (core) where only the central part is replaced. Posterior devices [3] cover three types of systems:

Peer-review under responsibility of the scientific committee of the 3rd CIRP Conference on BioManufacturing 2017
doi:10.1016/j.procir.2017.04.056

interspinous systems, systems that replace the facet joints, and pedicle systems [4]. Posterior devices with pedicle screws are able to preserve the integrity of the disc and the facets.

The lumbar segment studied here is implanted with an innovative posterior DSI (Fig. 1) consisting of two rigid metal elements (piston rod and fixed rod made of titanium) and deformable polymer elements inserted in the cylinder. The two rods are fixed to the pedicles of the lumbar vertebrae using titanium pedicle screws. The piston rod is connected to the upper vertebra (denoted n) and the fixed rod to the lower vertebra (denoted n+1). An assembly consisting of two DSIs and four pedicle screws is needed for one joint segment.

Fig. 1. Innovative concept for a dynamic spinal implant (articular segment **n/n+1**).

The main function of the assembly is to ensure the transfer of loads and to stabilize the lumbar segment during the three types of anatomical movement: flexion-extension, lateral inflexion and axial rotation. It must therefore allow mobility but also limit the range of relative movements. During extension movements by the patient the implants undergo compression. During flexion movements, they undergo traction.

Several solutions have been studied; this innovative concept has been validated by mechanical tests (quasi-static traction-compression, fatigue and aging accelerated by DMA), a key step in the design process devised for these medical devices [5] [6].

There is considerable intervariability in the range of displacement and the degree of the pathology in a significant sample of patients. The aim can never be to control these variations but to analyze them in order to design then optimize devices that perform their functions by incorporating natural fluctuations into these pathological situations. To do this, the optimization study is based on a structuring system (see section 3), involving Observation, Interpretation and Aggregation steps (OIA) which includes design constraints and the intended goals for the DSI.

A parsimonious model was developed, based on the geometry and mechanical characteristics of the assembly. The mechanical construction data for this model are derived from a previous experimental and bibliographic study, evaluating the displacements, the actions transmitted and their load distributions [7]. Thus the model that was constructed included mechanical behavior and these functional requirements. Sets of solutions were tested according to levels of degeneration (pathology); finally, a compromise was sought to meet the needs of a targeted sample of patients by developing the DSI.

2. Developing the mathematical model

The literature reveals essentially two types of modeling of the lumbar spine. The models most often produced are based on finite element (FE) methods. They study the local behavior of the vertebral column and include the non-linear mechanical behavior of vertebral segments (intervertebral disc), the influence of muscles and ligaments, etc. [8]. This detailed modeling is adapted to assess the state of stress of the elements of the vertebral segments after implantation.

The aim is to develop a predictive mechanical model during the design phase of a DSI; detailed FE models give access to stresses in all elements of the vertebra and the disc. This information is essential from a clinical point of view and during the validation phase of the technological solutions. In this study, we intend only to differentiate the positions of the constituent elements of the solutions and their intrinsic stiffness so as to adapt them as well as possible to the different degrees of disc degeneration. As a result, a simplified dimensioning tool is needed in this upstream solution search phase [9]. Different models can then be selected. In an earlier study, we used a model consisting of rigid bodies subjected to forces in mechanical equilibrium [10]. The main advantage of this model is that it is possible to assess the solution behavior with a very short calculation time (resolution of an analytical model); however, the equation system is associated with a single specific architecture of the solution. In order to put in place a tool that can be more generally applied, we develop a FE model consisting of beam elements and springs, using Matlab. The resolution times remain comparable but this model can evolve and one may envisage other architectures.

In this study, we model the mechanical behavior of a segment of the lumbar spine, taking into account the natural and postoperative asymmetries with respect to the sagittal plane (where the range of displacements is greatest during flexion or extension movements). The model is formulated based on relationships that represent the equilibrium of a mechanical system (Newton's first law). It can describe the natural behavior of the vertebral segment and its behavior after implantation of the DSI. The modeling process is described in the following paragraphs.

2.1. Disc degeneration and load distribution

According to the literature, the gradual degeneration of the disc produces a change in the load-bearing areas between the vertebrae. According to [10], when the disc is functioning in a standard way, the vertical load is mainly supported by the contact between the vertebra and the disc surface and is distributed between the anterior and posterior halves of the vertebra body. A fraction of the vertical load is taken up by the neural arch (around 8%). As a result of degeneration, this distribution changes considerably. Depending on the degree of degeneration, the load taken up by the neural arch can change from 8% of the vertical load to 63% in extreme cases. This variation is described in Table 1 based on cadaveric measurements [7] [10]. According to these measurements, in the lumbar region, the vertical load between vertebrae is 2kN.