Procedural Checks - IDE Master Graduation

TU Delft

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Dr. ir. Johan Molenbroek date 10 - 02 - 2020 signature johan molenbroek Digitally signed by johan molenbroek Date: 2020.02.10 21:53:05 +01'00'

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 23 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 23 EC

List of electives obtained before the third semester without approval of the BoE

(X) YES all 1st year master courses passed

( ) NO missing 1st year master courses are:

name _____ date 21-2-2020 signature

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: (V) APPROVED ( ) NOT APPROVED

Procedure: (V) APPROVED ( ) NOT APPROVED

- also approved for medisign
- no abbrevition in title, title will be listed on the repository, the diploma supplement, alumni database and ~~graduation~~ graduation calendar

comments

name Mr Meijer date 2-3-20 signature

Initials & Name DC Sarwin Student number 4278089

Title of Project Design of the surgical for a VCF device

Design of surgical instruments for a VCF device

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 04 - 02 - 2020 28 - 08 - 2020 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Spinal disorders are a leading driver of healthcare costs worldwide, and range in severity from mild pain and loss of feeling to extreme pain. One of the most common spinal disorders is vertebral compression fracture (VCF) with an occurrence of more than 1.5 million per year. VCF occurs when a vertebra becomes compressed due to trauma, which is in direct correlation with aging and the incidence of osteoporosis. Therefore, the risk of developing a vertebral fracture is strongly associated with decreasing bone density (Wong et al., 2019). Bone density automatically decreases after the age of 40 for both men and women, this process is rapidly accelerated in postmenopausal women. A multitude of lifestyle and environmental factors increase the risk of developing osteoporosis. These include a low body mass index and lack of exercise, insufficient dietary calcium, low vitamin D production/consumption, glucocorticoid medication, smoking and excessive alcohol intake (Ensrud & Schousboe, 2011).

The vertebral compression implies a reduction of the height and the increased angle between the upper and lower side of the vertebra compared to the adjacent vertebrae, as seen in figure 1. Patients with VCFs often experience severe back pain that may limits mobility and could lead to disability, and subsequently, increases mortality in an already vulnerable elderly population (Wong & McGirt, 2013). The goal of the surgical treatments is to regain the original position and angle of the vertebrae in order to solve the problems.

Current treatment, such as vertebroplasty and kyphoplasty, offer temporary solutions to patients, but are not without considerable complications. In all the treatments the major adverse events occur in more than 65% of the procedures. Besides, pain relief and patient satisfaction are disappointing. On top of that, in all treatments bone cement is used which could have fatal consequences for the patient.
(Du, Li, & Lin, 2014).

There is one product on the market which has a similar functional principle compared to Amber Implants' implant, which is called SpineJack and is manufactured by Vexim SA (lately acquired by Stryker).
In figure 2 we see the steps the procedure exists of;
1. Access Canula, insert canula into posterior one-third of vertebral body
2. Guidewire is inserted to the midpoint of vertebral body, to remove access canula
3. Reamer: follows the path of the guidewire, advance the reamer until it is entirely within the vertebral body
4. Template: template is now inserted to clean the implant site and verify the length of the implant
5. Unexpanded: two Spine Jacks are placed into the vertebral body
6. Spine Jacks expanded (without cement): Spine Jacks are expanded to reduce the fracture and restore the vertebral body's anatomy
7. Spine Jacks expanded (with cement): cement is injected to stabilize the fracture

space available for images / figures on next page

Initials & Name DC Sarwin Student number 4278089

Title of Project Design of surgical instruments for a VCF device