

Preclinical Assessment of Novel Radiopaque UHMWPE Sublaminar Wires in a Growth-Guidance System for Early Onset Scoliosis Correction

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Valorization

This thesis is the result of the Spineguide project, part of the BioMedical Materials research program, co-funded by the Dutch Ministry of Economic Affairs. Project members from Maastricht University Medical Center, Eindhoven University of Technology, the University of Twente and DSM Biomedical collaborated in this public-private partnership, each with their own specific focus within one of the different work packages. This project was driven by the unmet clinical need to provide a surgical solution for a small, but vulnerable and utmost challenging patient group.

The Spineguide project can be considered a very successful project, considering that FDA 510(k) clearance has been granted for certain specific intended clinical applications of the radiopaque UHMWPE sublaminar wires, thereby opening the doorway to clinical introduction. However, the UHMWPE wires have not been approved as an adjunct to spinal fusion or for application in pediatric patients. Application of the UHMWPE wires as described in this thesis will thus require institutional regulatory board approval for a controlled clinical trial. Moreover, realization has set in that in order for the radiopaque UHMWPE wires to be successfully marketed, a complete treatment system with surgical tools and with additional construct components should be offered, as was discussed in the General Discussion. A new project proposal for the development of a surgical toolset and additional construct components has been submitted to Chemelot InSciTe's (Institute for Science and Technology) Biomedical program entitled PoSTuRE was recently granted approval. Whereas the Spineguide project was primarily focused on the development and preclinical assessment of radiopaque UHMWPE sublaminar wires, this follow-up project (PoSTuRE: Patient-specific Scoliosis TREatment) will focus on the implementation of the whole treatment concept into clinical practice by further developing the complete surgical system, thereby optimizing ease of use for the surgeon and improving clinical outcome.

The incidence of early onset scoliosis is low, occurring in approximately 1-2 cases per 10,000 people in Europe [1]. Surgical rates for EOS have been reported to be approximately 30%-50% [2, 3]. With an annual birth rate of 5-6 million in Europe [4], this amounts to 150-600 potential patients in Europe and 5-18 patients in the Netherlands requiring surgery each year. Such low numbers do not normally provide enticing incentive to drive innovation or a solid basis for a business case for most commercializing parties. 75% of the total spinal device market is currently held by a total of five different medical device companies, with the largest two accounting for approximately 60% of the market revenue. Adoption of the developed technology by

one of the large medical device companies into their spinal portfolios is likely necessary for widespread clinical implementation. In order for this to occur, clinical feasibility results from a small patient cohort are necessary.

Although the commercial market size for EOS patients may not be very large, we do foresee a viable business case when scoliosis patient groups of all ages are targeted. Approximately 29,000 surgeries are performed annually in the USA to correct adolescent idiopathic scoliosis (AIS) [5]. The use of polymer sublaminar cables in hybrid constructs for the surgical treatment of AIS has been proven effective, with good correction of thoracic curves, low loss of correction in the long term, and superior correction in the sagittal plane [6]. We believe that UHMWPE sublaminar wires may also prove of great benefit in adult degenerative scoliosis patients whom often suffer from osteoporosis and as a result pedicle screw breakout and instrumentation failure. Osteoporosis generally leads to decreased bone mass in the anterior column of the spine, while the posterior structures, such as the lamina, remain mostly unaffected. Therefore UHMWPE sublaminar wires may be used as a substitute for pedicle screws or may be used as a means to reinforce pedicle screws. Furthermore, as UHMWPE sublaminar wire fixation leads to slightly less rigid fixation in comparison to pedicle screws, placing UHMWPE at the cranial end levels of the instrumented segment may lead to a decreased incidence of proximal junctional kyphosis (PJK) and its associated problems such as adjacent level fractures or instrumentation failure.

The potential market size for UHMWPE sublaminar wires within adult spinal deformity (ASD) surgery is substantially larger and is also vastly increasing due to the aging population. The number of surgeries performed for adult spinal deformities has doubled in the past decade, from 9,400 in 2000 to more than 20,000 in 2010 in the USA alone [7]. This rapid increase is astonishing, as the frequency of all other spine primary diagnosis codes increased by a mere 20% over the same time period. These numbers were taken from the Nationwide Inpatient Sample (NIS) database [8], which approximates a 20% stratified sample of US community hospitals [9]. Therefore, the total number of ASD surgeries can be estimated at 100,000 in the USA alone in 2010, with current numbers at approximately 150,000 if the rapid increase has continued in the past five years. Of these patients, between 9-17% experience severe instrumentation related problems such as screw pullout or proximal junctional failure that necessitate revision surgery [10, 11]. The direct costs of revision surgery in adult spinal deformity patients amount to approximately \$67,000 on average [12]. Decreasing the incidence of severe instrumentation failure related problems and their associated costs is therefore of great clinical and societal importance.

Government funding for this and future projects is justified as the newly proposed growth guidance system may prove to increase quality of life and significantly lower healthcare costs for the treated patients. Cost-effectiveness analyses have been

performed for magnetically controlled growing rod (MCGR) systems in comparison to conventional growing rod systems (CGRS) in the UK [13]. This study provides valuable insight into the possible healthcare savings which may be attained with the newly proposed growth guidance system. The initial costs for CGRS are approximately £8500 (€11,500). Lengthening costs, consisting of operating room and postoperative care costs, amount to approximately £6,500 (€7,700) annually for CGRS (two procedures per year). For the newly proposed growth guidance system, we expect the initial costs to be similar to the CGRS: approximately €11,500. However, no lengthening procedures are required. The costs of lengthening procedures have been calculated to amount to approximately £32,500 (€38,500) for the CGRS over a five year period. So, this entire amount can potentially be saved per patient with the newly proposed growth guidance system. Lower expected costs and no required return to hospital for lengthening procedures may be decisive factors to favor growth-guidance systems over MCGR (or conventional GR systems), especially in developing countries. Furthermore, a definitive fusion procedure is usually required to attain maximum correction of the deformity upon reaching skeletal maturity with both CGRS and MCGR. With the newly proposed system, rod fixation in the middle of the curve (apex) is also applied, which would result in superior correction. Therefore, revision procedures are expected to be required less frequently. Most importantly, a definitive fusion procedure can potentially also be avoided due to the superior correction attained with the newly proposed growth guidance system. This would result in further cost savings which amount to an additional €25,000-€30,000 if a definitive fusion procedure can be avoided. Not only in direct costs, but as the quality of life for the patients will increase and the associated morbidity will be less, the indirect health care costs will also be lower.

The PoSTuRE project intends to demonstrate safety of radiopaque UHMWPE sublaminar wires via a first-in-man study in adult degenerate scoliosis patients. The additional to-be developed instrumentation system components will be tested in animal trials first. If successful, the results of both these studies will justify a trial in juvenile scoliosis patients. These clinical trials are intended to provide proof of safety. Supported by background information on the material (i.e. Dyneema Purity® Radiopaque fiber master-file) and production processes, an application for CE marking or FDA approval can then be submitted. Once approval is obtained, larger scale multi-center (randomized) clinical trials can be initiated. Once efficacy has also been proven, the Spineguide treatment concept can be introduced to market on a global scale. Medtronic is currently the market leader in Spinal Surgery Devices, with well over 35% market share, and is involved in the project by supporting the development of the surgical tools. This puts them in an ideal position to closely monitor the progress and outcomes of the project. They would be the ideal partner to bring the PoSTuRE treatment system to market, and the close proximity to the project makes opening discussions with them easy.

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