Clinical rationale and in vivo assessment of novel radiopaque UHMWPE sublaminar wires in growth-guidance surgery for early onset scoliosis

VALORIZATION

This appendix describes the social and economic value of the results described in this thesis.

Early onset scoliosis (EOS) is defined as scoliosis of any etiology before the age of 10.[1] The incidence of EOS in Europe is 1-2 per 10,000 people.[2] In 10% of EOS patients the deformity will progress to a severe and disabling condition.[2, 3] Because of the substantial residual growth, the originally orthopedic problem, may become a serious pediatric systemic disorder. Because of reduced height of the thoracic spine, thorax insufficiency can cause serious pulmonary problems.[4] EOS requires special attention as the deformity occurs in very young children and without treatment it will progress to cosmetic disfigurement and poor quality of life, mainly caused by the abovementioned thorax insufficiency syndrome.[4-6] Orthotic bracing and casting generally have limited effectiveness due to thorax and spine compliance, pulmonary compromise and skin breakdown.[7] If early spinal fusion is performed, spine and thoracic growth are restricted, resulting in severe pulmonary compromise. Negative outcomes of conservative treatment and concomitant morbidity of EOS patients lead to substantial medical costs.

In the past years, EOS has become an emerging field of spinal surgery. Advancements in implant technology have led to various techniques of spinal instrumentation, which have made severe deformities become correctable. However, in the growing young child correcting the curve is not always synonymous with treating the disease.[8] With the increased insight in the negative effects of early spinal fusion, fusionless techniques have emerged. Although there still are many unresolved issues regarding the fusionless instrumentation methods, it has become clear that these techniques can improve the quality of life of these small children both by negating the requirement for long-term external immobilization, and by effectively controlling the deformity while facilitating spinal growth and lung development.[8] As a result of the distinctly different etiologies of EOS and a shortage of evidence-based clinical research, the treating physicians will rely on their clinical experience and knowledge to form a treatment plan.[8] Consequently, there is no consensus between surgeons with regard to the optimal surgical treatment and the decisive growth-friendly instrumentation.[9] The term growth instrumentation seems somewhat

misleading, as the 'growth' often requires surgical lengthening, which is especially the case in spine-based and rib-based distraction surgery. These repeated surgeries have severe effects on the general health of the patients and can also affect the psychological state of the children and parents.[10] Matsumoto et al have shown that when patients were of younger age at the initial time of surgery and had an increasing number of repetitive surgeries, psychosocial scores diminished.[10] In traditional growing rod (TGR) surgery, which requires repetitive procedures, the overall wound complication rate is 16% increasing with 24% during each additional surgery.[11] Magnetic controlled growing rods (MCGR) avoid the need for repeated surgical intervention and early results are promising. Long-term data are not yet available for this technique. Similar to other growth-friendly implants, the complication rates are still high.[12] Implant related complications, such as rod fracture, implant dislodgement and proximal junction failure have been reported in both distraction surgery and growth-guidance surgery. [13-15]

The Spineguide project, resulting in this thesis, was started as 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 expertise within one of the different work packages. This partnership finds its origin in a common concern and interest in a young vulnerable and challenging patient group for whom optimal treatment should become available.

In this thesis we have assessed the feasibility of UHMWPE wires as sliding anchors along a dual rod instrumentation system for the treatment of early onset scoliosis (EOS). The mechanical properties of the UHMWPE cables were shown to be superior to other sublaminar cables or wires in terms of tensile and fatigue strength, while possessing stiffness at least comparable to metal cables.[16] Using UHMWPE sublaminar wires in a growth-guiding instrumentation has several important advantages: the occurrence of metal wear particles and concomitant tissue reactions will be minimized, hardware failure as a result of wire breakage will be diminished because of the high fatigue strength, while continued spinal growth will be facilitated by low friction characteristics. Radiopacity of the wires can preclude false routing and instability of the wires. Whilst optimal anchoring sites (e.g. apical

pedicle screw fixation) still have to be determined, we expect that a growth-guidance system consisting of these radiopaque UHMWPE sublaminar wires will be worth considering because of the reduced complication rate and acceptable medical costs.

Industry and clinicians should consider health-care economics prior to testing or initiating any new treatment or medical device. Besides a French cost analysis study comparing MCGR and TGR[17], no studies reporting current costs of EOS management have been described. The MCGR system is recently CE marked but its use may be limited as a result of the substantial costs of this device. The unit costs of the MCGR system varies from 23,000 to 33,000 € in France to 5,200 € in China, depending on the type of construct.[17] Charroin et al. stated that the estimated costs of traditional growing rod (TGR) surgery and MCGR systems were respectively 49,067 € and 42,752 €. In case of TGR surgery, increased hospital stay expenses due to the need for repetitive surgery resulted in incremental costs. The costs of the MCGR systems contributed to 59.5% of the total amount.[17] No cost analysis studies have been performed on the use of growth-guidance systems in EOS surgery. However, it is to be expected that with the use of growth-guidance systems medical costs are reduced. System costs are expected to be lower (compared to MCGR) as well as the number of re-operations (compared to TGR). If a definitive fusion procedure can be avoided, which is often performed after growing rod surgery, the overall morbidity, psychological impact and medical costs may further decrease. Future research and clinical studies have to determine feasibility, specific indications and cost-effectiveness of growth-guiding surgery using UHMWPE wires. It would be interesting to compare such results to those of the use of MCGR.

The results of this thesis can contribute to future preclinical assessment of growth-friendly instrumentation in EOS surgery and animal research scoliosis studies. The Spineguide project successfully led to FDA clearance for the use of radiopaque UHMWPE wires in certain indications in spinal trauma surgery. Considering ongoing insights, future research will determine the feasibility of a definitive growth-guiding system including radiopaque UHMWPE gliding anchoring and the amount of required fixation points. UHMWPE wires have not been approved for application in pediatric patients in growth-guiding surgery yet. A follow-up project (PoSTuRE: Patient-specific Scoliosis TREatment, a new recently granted Biomedical program) will focus on the clinical implementation of the proposed

UHMWPE sublaminar wires. Other interesting applications of the wires, for which regulatory approval would need to be obtained, are supplementary fixation in degenerative scoliosis surgery and as cerclage wires in (periprosthetic) fracture fixation.

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