CD8 T-cell subsets as biomarkers for predicting non-fusion after spinal bone fusion surgery

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Background
Chronic lower back pain is one of the major reasons for disability and early work retirement in the industrial world which can result from serious problems like degenerative disk disease, displacement of disk, spinal stenosis, spondylolisthesis, and spondylosis. After intensive physiotherapy, patients often undergo spinal bone fusion surgery to stabilize the spine and reduce pain. Between 1998 and 2008, the annual number of spinal fusion in US increased 2.4-fold from 174,223 to 413,171 (Rajaee et al. 2012). In 2011, 488,000 spinal fusion surgeries were reported for US, which represents 3.1% of all OP’s (6th rank). With 27000 Dollar per case, the spinal fusion treatment is a very expensive surgical treatment. Also in Germany the spinal fusion surgery strongly increased with 229206 spinal fusion treatments in 2011. However, successful fusion rate (de novo bone formation) following spinal fusion surgery is limited (between 46-100%). Biological deficiencies, comorbidities and the bone graft material affect the outcome of spinal fusion. There is an unmet need for biomarkers predicting the outcome of spinal fusion surgery to early identify patients who would benefit from a supporting treatment with growth factors, like BMP.

Technology
The invention relates to a method for predicting the probability of having or developing a non-fusion, particularly before undergoing a spinal fusion surgery or before revision surgery in failed spinal fusion or after a spinal fusion surgery. The method comprises determining the frequency of a specific subpopulation of CD8+ effector cells expressing the phenotype CD8+CD3+CD45+CD57+ or CD8+CD3+CD45+CD28- or CD8+3+45+57+28-. In a study with spinal fusion patients (N=44), the non-union patients (N= 21) classified by radiological and time dependent criteria, show a significantly enhanced frequency of the specific differentiated CD3+8+28- and/or 57+ T-cells in the peripheral blood 24 weeks post-OP.

Benefits
✓ Early prediction of spinal non-union helps early stratifying risk patients and therapeutically support the healing process by administering growth factors (e.g. BMP)

Application
Prediction or detection of non-fusion after spinal fusion surgery

Commercial Opportunity
Searching for a licensing or developing partner

Fig. 1: Significantly higher frequency of CD3+8+57+ T cell expression (in %) in spinal non-fusion patients (N= 21) compared to patients with normal spinal fusion (N= 23) 24 weeks post-OP (spinal fusion OP).

Key words
Biomarker, prediction, spinal fusion surgery, CD8 T-cell subsets

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