

**NYU**

Osteoarthritis (OA) Biomarker Suitable as a Point-of-Care Diagnostic

Technology

A team of leading researchers from NYU Langone Health Orthopedic Hospital and Duke University have identified TSG-6 activity as a synovial fluid biomarker that is significantly associated with the risk of radiographic osteoarthritis (OA) progression, and the incidence of total knee replacement (TKA) over a 3-year period. TSG-6 (Tumor necrosis factor (TNF)-stimulated gene-6 protein) is a 35-kDa protein induced in a wide range of cell types in response to inflammatory mediators. TSG-6 catalyzes the covalent transfer of large polypeptides (termed Heavy Chains, HCs) onto hyaluronan, from the serum proteoglycan inter- α -inhibitor (Ial); a serine protease inhibitor). The inventors have developed a solid phase substrate that can measure this TSG-6 activity using low volumes of synovial fluid, with associated colorimetric development. The measured activity is not identical to the measured quantity of TSG-6, because multiple factors in synovial fluid can influence this reaction.

Background

Osteoarthritis affects more than 25 million Americans, and the majority of individuals over age 65. The characteristics of the disease and its progression are highly variable between patients. Current treatment is based on clinical and radiologic evaluation. Because of the poor correlation between radiologic findings and clinical symptoms, a biomarker is needed to identify patients at risk of rapid progression, and to determine the extent of inflammation in the affected joint. A global measure of local disease activity has the potential to inform clinical treatment and the timing of joint surgery.

Applications

- Point-of care diagnostic to inform treatment of patients with knee OA
- Identification of patients at risk of rapid OA disease progression
- Identification of patient populations suitable for clinical trials of disease modifying drugs
- Identification of patients amenable to anti-inflammatory therapies
- Screening of patients with acute knee trauma to monitor inflammatory reaction to trauma

Advantages

- Requires only low (μ L) quantities of synovial fluid for measurement. The necessary volume of synovial fluid can be recovered from most patients.
- Measures TSG-6 activity, rather than quantity and is based only on reactants contained within the synovial fluid sample. No additional reactants need be added and it can be readily developed into a colorimetric point-of-care assay, using standard reagents for color development.
- Particularly relevant for patients undergoing intra-articular treatment.
- TSG-6 activity highly correlates with multiple biomarkers of inflammation, and may serve as a global biomarker of local inflammation in joints.

Technology ID

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Category

Life Sciences/Diagnostics

Life

Sciences/Therapeutics/Autoimmune Disease

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