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Tissue-engineered medical products — Evaluation of anisotropic structure of articular cartilage using DT (Diffusion Tensor)-MR Imaging

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National foreword

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Foreword

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The committee responsible for this document is ISO/TC 150, *Implants for Surgery*, Subcommittee SC 7, *Tissue-engineered Medical Products*.

Introduction

Structural evaluation of articular cartilage with conventional diagnostic technologies is challenging, and Nihon University has developed technologies (see Reference [1]) and collected relevant data for *in vivo* evaluation of articular cartilage structure by means of diffusion tensor magnetic resonance imaging (DT-MRI) using 1,5 Tesla or 3 Tesla MRI equipment employed for treatment in hospital settings. These data are released in this Technical Report prepared for reference in treatment settings.

This work is part of "Development of Cartilage Observation and Evaluation Technologies for Regenerative Medicine Processes", an activity managed by the University under "Development of Evaluation Technology for Early Introduction of Regenerative Medicine", a project contracted by the New Energy and Industrial Technology Development Organization (NEDO) to the National Institute of Advanced Industrial Science and Technology (AIST) and its Technology Research Association of Medical Welfare Apparatus.

Tissue-engineered medical products — Evaluation of anisotropic structure of articular cartilage using DT (Diffusion Tensor)-MR Imaging

1 Scope

This Technical Report has been prepared for evaluation of therapeutic courses for articular cartilage disease and summarizes results from structural evaluation of knee joint cartilage by diffusion tensor imaging, an MRI applied technology allowing non-invasive observation of soft tissue morphology *in vivo*.

This Technical Report is intended for use in areas such as regenerative medicine for knee joint cartilage disease.

After *in vivo* transplant of cartilage cells or tissue as a regenerative treatment, longitudinal diagnosis is needed to assess regeneration as articular cartilage, but arthroscopes used primarily for this purpose are invasive and also do not allow evaluation of structure by simple observation of surfacial characteristics. Radiography and CT do not visualize articular cartilage and also entail the problem of exposure. Collagen fibres, the primary component of articular cartilage, have a surfacial layer parallel to the articular surface to serve a lubricating function for the articular surface, a middle layer with a randomized structure to distribute loads, and deep layers oriented vertically to support loads. The anisotropy of this three-layer structure is a characteristic feature of hyaline cartilage structures and a mechanism demonstrating a lubricating function for articular cartilage. We can then ask whether articular cartilage can be assessed by evaluating the anisotropy of collagen.

MRI techniques allow non-invasive visualization of soft tissue form and function *in vivo*, and DT-MRI conveys the direction of water molecule motion. In fibrous tissues, the direction of water molecule motion is restricted to the direction of fibre orientation; consequently, the direction of water molecule motion matches that of fibre orientation. The use of DT-MRI therefore does allow evaluation of collagen fibre orientation and anisotropy in articular cartilage.

DT-MRI is thus used to observe articular cartilage anisotropy data for use as standardized data in longitudinal diagnosis following transplant of articular cartilage as a regenerative treatment.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
diffusion tensor
DT
tensor expressing the orientation and magnitude of diffused proton signals

2.2
sequence
protocol for performance of MRI

2.3
spin-echo echo-planar imaging
SE-EPI
method of high-speed imaging in which gradient fields are flipped continuously at high speed to produce echoes continuously by means of a spin-echo pulse sequence

