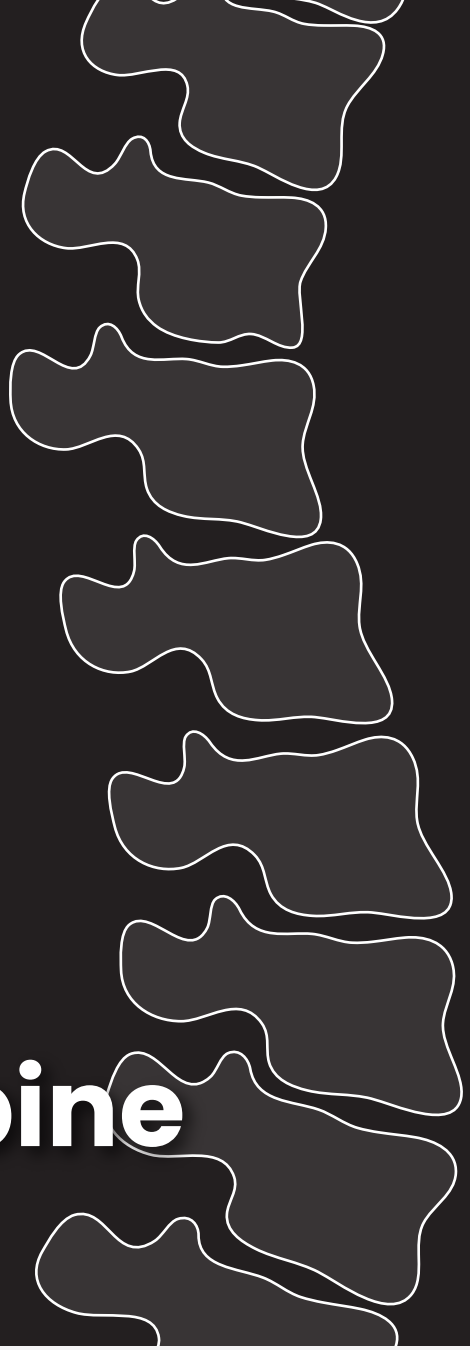
FDA 510(k)-cleared CE 2460

HIPAA COMPLIANT

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 748864



Swift Imaging
Reliable Reading

SwiftMR™
Case Report | Spine

Introduction

Magnetic Resonance Imaging (MRI) is a non-invasive radiologic examination which does not produce ionizing radiation like X-ray imaging and Computed Tomography (CT). Due to superior soft tissue contrast and image resolution, MR is an important part of clinical practice in making accurate diagnosis, monitoring therapeutic response, and follow-ups. Despite these advantages, however, MR exams typically require long scan times – limiting its use compared to other modalities. To this effect, numerous research and technical developments are now focused on reducing the scan time to increase scanner efficiency and improving the patient experience.

SwiftMR™ is FDA 510(k)-cleared* deep learning (DL)-based software medical device developed by AIRS Medical. SwiftMR™ reduces image noise and increases sharpness of MR images based on its vast training dataset of high-quality MR images.

The following clinical cases were collected from research conducted at Seoul National University Hospital (Seoul, Korea). This study was approved by the institutional review board (IRB) and informed consents were received from all enrolled patients. The purpose of this study was to clinically evaluate the quality of spine (C-Spine, L-Spine) images processed with SwiftMR™, where input images were acquired at were acquired under reduced scan time compared to the institutional conventional. To do this, images were acquired from enrolled patients using both conventional and faster scan protocol, then images were compared after applying SwiftMR™ to the latter.

* FDA 510(k)-cleared for Standard of Care (SOC) and reduced scan time MR images for all body parts. Supported field strength may vary by country.

C-Spine

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Image qualities between the conventional images and accelerated images processed with SwiftMR™ were compared in a prospective study.

Case #1

23 y/o | Female

C-Spine SAG T2WI FS

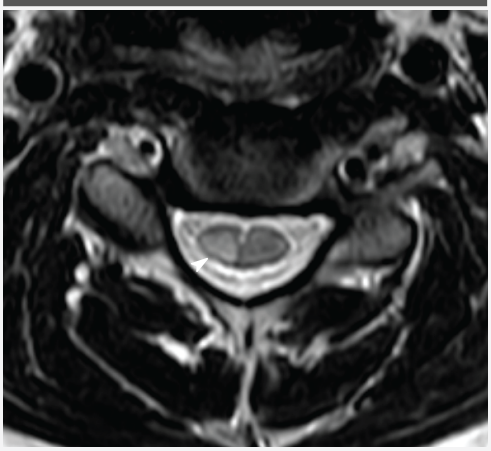
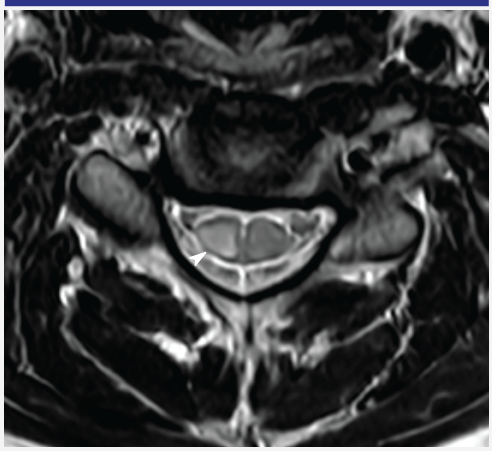
2D TSE-mDIXON
Acquisition voxel size:
Ⓛ 0.9×1.1×3.0 mm
Ⓡ 0.9×1.1×3.0 mm

Conventional	SwiftMR™*
	
Scan time 03:10	Scan time 01:41

Focal high T2 signal lesion (white arrowheads) can be seen at the C4-5 level spinal cord of both images. Although linear high T2 signals due to truncation artifact (black arrowheads) can be seen in both images, image processed with SwiftMR™ shows relatively more homogenous normal spinal cord signal.

C-Spine AX T2WI

2D TSE
Acquisition voxel size:
Ⓛ 0.6×0.8×4.0 mm
Ⓡ 0.6×0.8×4.0 mm

Conventional	SwiftMR™*
	
Scan time 01:48	Scan time 00:58

Although both images show focal high T2 signal lesion (white arrowheads) at the C4-5 level spinal cord, image processed with SwiftMR™ displays better delineation of the lesion from the surrounding normal spinal cord. In is worth noting that flow artifacts due to CSF flow is relatively more distinguished in the SwiftMR™ image, but spinal cord-CSF boundary is better expressed with SwiftMR™ compared to the conventional.

* For investigational purpose only

Case #2

58 y/o | Male

C-Spine
SAG T2WI

2D TSE
Acquisition voxel size:
Ⓛ 0.8×1.1×3.0 mm
Ⓡ 0.8×1.0×3.0 mm

Conventional

Scan time 02:37

SwiftMR™*

Scan time 01:24

Both images display moderate central canal stenosis at C3-4 level due to ossification of posterior longitudinal ligament (OPLL, black arrowheads) and mild central canal stenosis at C5-6 level due to disc bulging (white arrowheads). However, SwiftMR™ image displays relatively higher SNR and spatial resolution, leading to less coarse image perception and better delineation of normal anatomies such as vertebral body, spinal cord and intervertebral discs.

C-Spine
SAG T1WI

2D TSE
Acquisition voxel size:
Ⓛ 0.8×1.1×3.0 mm
Ⓡ 0.8×1.1×3.0 mm

Conventional

Scan time 02:51

SwiftMR™*

Scan time 01:30

Both images equivalently show ossified posterior longitudinal ligament (white arrowheads) at the C3-4 level. However, SwiftMR™ image displays relatively higher SNR and spatial resolution, leading to less coarse image perception and better delineation of normal anatomies such as vertebral body, spinal cord and intervertebral discs. Also, standard image displays artifact (black arrowhead) of unclear origin at the C6-7 level, which is not shown in the SwiftMR™ image.

* For investigational purpose only

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L-Spine

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Department of Radiology, Seoul National University Hospital, Korea
Image qualities between the conventional images and accelerated images processed with SwiftMR™ were compared in a prospective study.

Case #1

57 y/o | Female

L-Spine SAG T2WI

2D TSE
Acquisition voxel size:
Ⓛ 0.8×1.1×3.0 mm
Ⓡ 0.7×0.8×3.0 mm

Conventional	SwiftMR™*
	
Scan time 02:32	Scan time 01:41

Intervertebral discs are clearly discernable from vertebral endplates in both images, and annulus fibrosus equivalently shows lower T2 signal intensity compared to nucleus pulposus in all L1/2, L2/3, L3/4 discs in both images. Also, lower T2 signal intensity and disc bulging (arrow) in L4/5, L5/S1 discs due to degenerative change is shown in both images.

L-Spine AX T2WI

2D TSE
Acquisition voxel size:
Ⓛ 0.7×0.9×4.0 mm
Ⓡ 0.7×0.7×4.0 mm

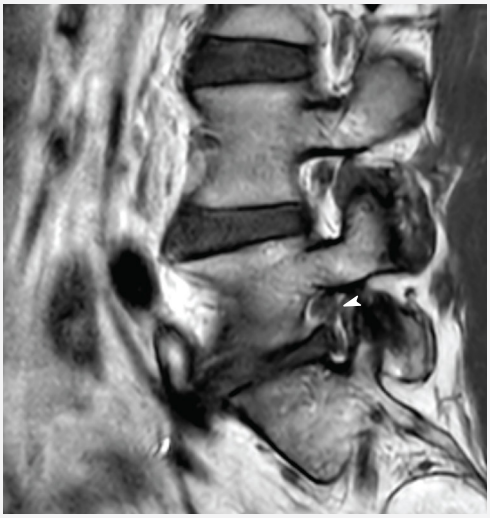
Conventional	SwiftMR™*
	
Scan time 02:23	Scan time 01:32

Image processed with SwiftMR™ shows clearer depiction of individual cauda equina nerve roots and the surrounding cerebrospinal fluid (CSF) compared to the conventional image. Also, high T2 signal details in paraspinal muscles such as fascicles and fascia (arrows) are enhanced with SwiftMR™.

* For investigational purpose only

L-Spine
SAG T1WI

2D TSE
Acquisition voxel size:
Ⓛ 0.8×1.1×3.0 mm
Ⓡ 0.7×0.9×3.0 mm

Conventional	SwiftMR™*
	
	
Scan time 02:34	Scan time 01:43

Both images accurately show normal homogenous T1 signal of vertebral yellow marrow structure, and normal fat tissues surrounding the nerve roots in the neural foramen at L4/5 level. Also, moderate neural foraminal stenosis at L5/S1 level due to facet arthrosis and herniating disc is clearly depicted in both images.

* For investigational purpose only

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Case #2

64 y/o | Male

L-Spine SAG T2WI

2D TSE
Acquisition voxel size:
Ⓛ 0.8×1.1×3.0 mm
Ⓡ 0.7×0.8×3.0 mm

Conventional

Scan time 02:46

SwiftMR™*

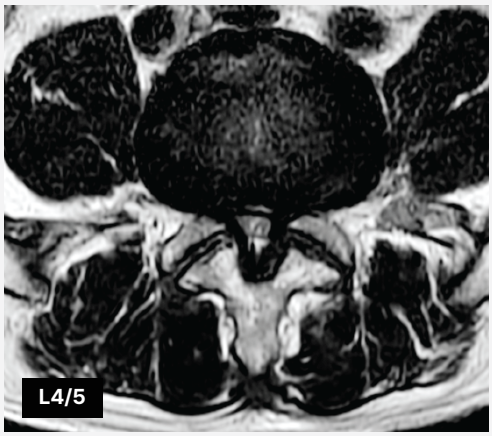
Scan time 01:50

Intervertebral discs are clearly discernable from vertebral endplates in both images. Also, both images clearly show ① lower disc T2 signal and bulging due to degenerative change, ② annular fissure in the annulus fibrosus of L4/5 disc and ③ central canal stenosis at the L2/3, L3/4, L4/5, L5/S1 levels. It is worth noting that an endplate compression fracture at L4 in this osteoporotic patient was previously unclear in the conventional image, but clearly shows low T2 signal intensity (arrow) in SwiftMR™ image.

L-Spine AX T2WI

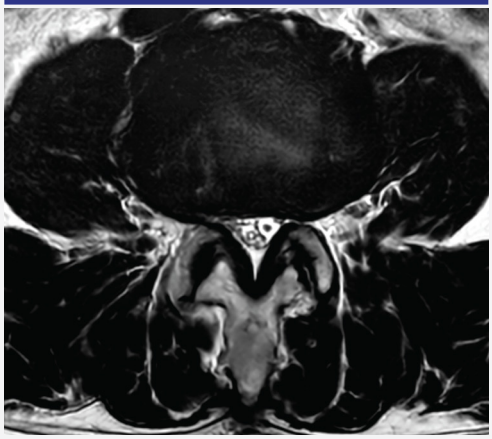
2D TSE
Acquisition voxel size:
Ⓛ 0.7×0.9×4.0 mm
Ⓡ 0.7×0.7×4.0 mm

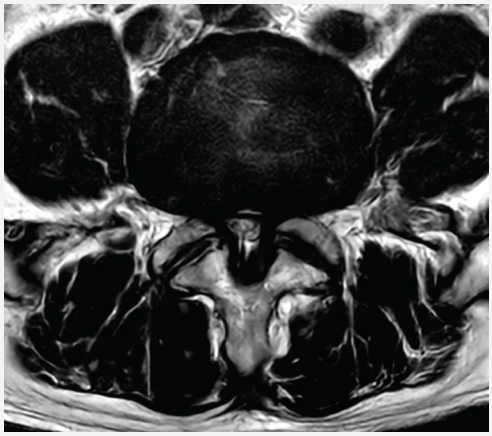
Conventional



Scan time 01:49

SwiftMR™*





Scan time 01:11

Mild central canal stenosis due to L2/3, L3/4 disc herniation and severe central canal stenosis at L4/L5 level is equivalently shown in both images. However, SwiftMR™ image provides better description of individual cauda equina nerve roots and surrounding CSF in the central canal.

* For investigational purpose only

L-Spine
SAG T1WI

2D TSE
Acquisition voxel size:
Ⓛ 0.8×1.1×3.0 mm
Ⓡ 0.7×0.9×3.0 mm

Conventional	SwiftMR™*
	
Scan time 02:34	Scan time 01:43

Both images show inhomogenous T1 signal intensity in vertebral bodies due to red and yellow marrows.

* For investigational purpose only

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