Intervertebral Disc Dehydration

- Degenerated intervertebral discs accumulate lactic acid causing pH levels to fall as low as 5.75
- Lactic acid alters cellular activity by down-regulating Proteogylcan (PG) synthesis and up-regulating enzymes that degrade the extracellular matrix.
- A low pH impairs the ability of PG to bind water causing the disc to degenerate and appear black under imaging

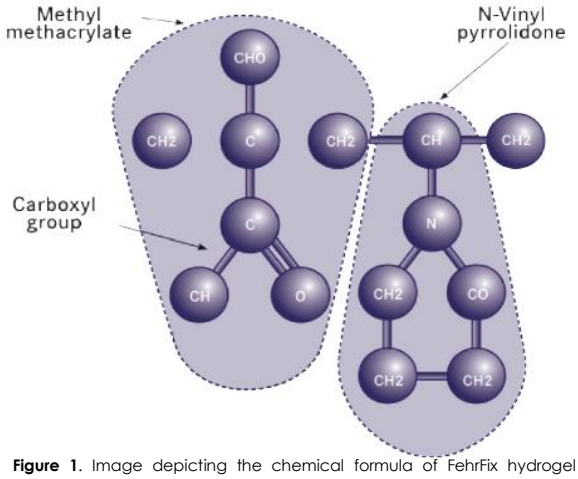


Figure 1. Image depicting the chemical formula of FehrFix hydrogel compound. Stable, dry material, made of cross-integrated hydro gel: Copolymers are based on methyl methacrylate and N-Vinylpyrrolidone

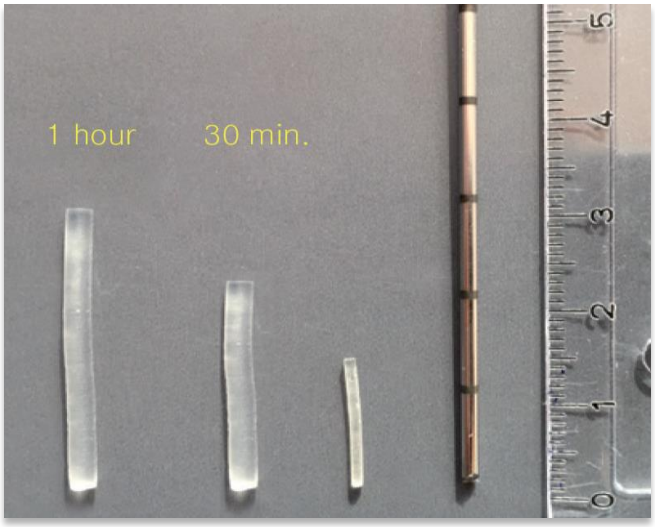


Figure 2. Image depicting FehrFix implants. Preoperatively implants are in a dry, non-inflated state and holds that rigid form and shape. Once implanted into the disc nucleus, they absorb natural body fluids as they hydrate and expand continuously to a controlled and predefined size and shape. Implants can absorb as much as 10 times their pre-op weight

What is FehrFix?

- A non-surgical treatment for discogenic pain in the early stages of 'Degenerative Disc Disease' or when surgical intervention is undesirable or contraindicated
- FehrFix introduces a hydrophilic material (**hydrogel**) into the disc nucleus
- In-Situ volume expansion of the hydrogel restores natural hydration, pressure and stabilizes the pH in the nucleus to healthier levels
- FehrFix hydrates through the absorption of the body's own fluids
- The self-swelling hydrogel pins act upon the osmotic principle to gain volume

FehrFix Hydrogel Implants

- High Biocompatibility – non-toxic
- Low Tissue Adherence
- Permeable to water soluble compounds
- Elasticity controlled by water
- Strength & Elasticity similar to tissues such as nucleus polposus & cartilage

Implant Procedure

- Non-surgical intervention under local anaesthesia
- Minimal trauma using cannulated needle
- Implant Inserted through a 17-gauge needle
- No pressure peaks occur
- ~15 minute procedure time

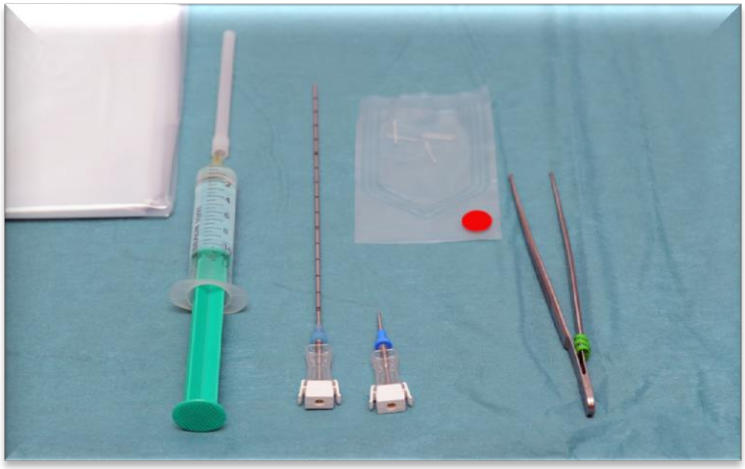
FehrFix Clinical Information

Study #1

- 13 Patients
- All with back and leg pain
- 10/13 (**77%**) Pain free or significant improvement
- 3 Patients required surgery (two after 6 months and one after 4 months)

Study #2

- 17 Patients
- 16 with back and leg pain plus 1 with leg pain
- 15/17 (**88%**) Pain free or significant improvement
- 2/17 patients required a fusion due to disc collapse



Indications

- Symptomatic lumbar DDD up to two segments.
- Dominant lumbar back pain with or without pseudo-radicular symptoms for more than 12 weeks, changes in MRI
- No improvement after minimum 12 week's conservative treatment with physiotherapy and pain drugs.
- No age limit
- Visible disc changes on MRI
- Minimal facet degeneration
- Annulus should be largely intact, HIZ (high intensity zone) is not contraindicated
- VAS Pain Score >3

Contraindications

- Radiculopathy by nerve compression
- Stenosis, Spondylosis, Spondylolisthesis, acute fracture or Spondylitis at the treated segment.
- Modic type >2 or serious changes on endplates.
- Pregnancy