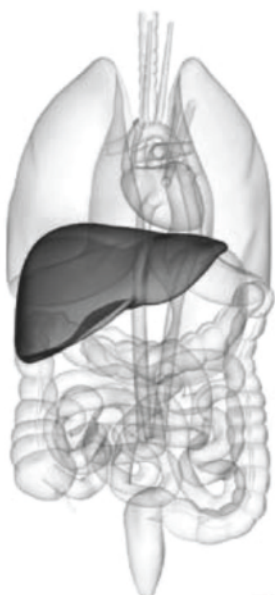


FibroScan®



What is FibroScan®?

Fibroscan®, also called transient elastography, is a technique used to assess liver stiffness (in kilopascal) which is correlated to fibrosis and at the same time indicates fatty liver (in decibels per metre), without human body intrusion.

With the results, it shows the evolution of the liver health and allows physicians to diagnose and monitor disease evolution regardless of treatment or collateral factors.

This also helps to anticipate various complications, as well as to monitor and assess the damages caused by diseases such as cirrhosis.

This is a rapid, painless and completely non-invasive examination of your liver.

FibroScan® quantify the stiffness of the liver and give an approximation of fat in the liver. It is able to evaluate whether there is any significant fibrosis or hardening of the liver. It is used in the clinical management of patients with liver disease such as chronic viral hepatitis C and B and fatty liver diseases.

How does the FibroScan® device work?

The fibroscan® device works by measuring shear wave velocity and attenuation rate of the ultrasound wave simultaneously.

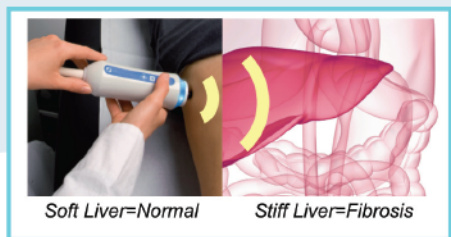
VCTE™ (Vibration Controlled Transient Elastography) is based on the transmission of mechanical energy through the patient. The mechanical vibration can be compared to a flick; the energy amount is very small compared to shear waves caused by organs such as the heart or respiratory motions. **The vibration is controlled and monitored during the examination.** These amounts of energy only depend on the probe model; they do not vary between stiff or soft livers.

VCTE™ is a **non-invasive method** which quantifies tissue stiffness using only small mechanical and acoustic energies. The transducer is able to measure the velocity of the shear wave as it passes through the liver. The technology measures the velocity of the sound wave passing through the liver and then converts that measurement into a liver stiffness measurement, which is expressed in kilopascals (kPa).

What it simply means is that, it does this by mechanically generating an ultrasound wave that travels through the liver and measuring the speed of the wave. The speed of the wave is dependent on how “soft” or “hard” the liver is. Studies have already been done which match the speed of the wave of liver stiffness and hence amount of liver fibrosis or “hardening”.

At the same time, the attenuation rate of the ultrasound is also measured using CAP™ (Controlled Attenuation Parameter) on the same volume of tissue. This measures hepatic steatosis or fatty liver and is expressed in decibels per meter (dB/m). CAP™ is not affected by existing fibrosis and inflammation in the liver.

The entire process is often referred to as Liver Ultrasonographic Elastography.



DUAL FUNCTION Liver Diagnostics

STIFFNESS ASSESSMENT



- Mechanically induced 50 Hz shear wave
- Measure shear wave speed with pulse echo ultrasound
- Liver stiffness calculated and expressed as a median over 10 measurements

VCTE™



- Large 3 cm³ sample size compensates for liver tissue heterogeneity
- Liver stiffness and attenuation rate assessed from the same measurements
- Exploration volume of 3 cm³ is over 100x than with needle biopsy¹

CONTROLLED ATTENUATION RATE



- CAP™ is computed from the ultrasound acquired for stiffness measurement
- CAP™ is only calculated if the stiffness acquisition is valid
- CAP™ is expressed in decibel per meter (dB/m)

CAP™

How should I prepare for the procedure?

- You should wear comfortable, loose-fitting clothing.
- A fasting period of 3 hours is required for the scan.

How is the procedure performed?

You will lie on your back. The radiographer will apply a water-based gel to the skin, to help the transducer make secure contact with the skin. The sound waves produced by the transducer cannot penetrate air, so the gel helps eliminate air pockets between the transducer and the skin. The probe

is placed along the inter-costal space near the right lobe of the liver with a slight pressure.

The examination includes 10 consecutive measurements made at the same location.

When the examination is complete, the gel can be easily cleaned with the use of tissue and you may be asked to dress and wait while the images are reviewed.

In case of close follow-up, the examination can be safely repeated.

If an ultrasound scan of the liver is done, is a FibroScan® still needed?

Fibroscan is a completely different scan from a typical ultrasound scan. It is indicated in patients with fatty liver disease, hepatitis B, hepatitis C, alcoholic liver disease and other forms of liver disease. You will still need a normal ultrasound scan to detect tumours, but only fibroscan can tell you whether there is any significant liver damage or fibrosis well in advance of an ultrasound scan.

Is it painful?

No. The examination is painless, quick and easy. During the measurement, you will feel a slight vibration on the skin at the tip of the probe.

What are the benefits versus risks?

Benefits:

- No pain and most scans can be completed within 10 minutes.
- It is non invasive and does not require sedation.
- It is less expensive than a liver biopsy.
- It is safe and does not use any ionising radiation.

Risks:

- There are no known harmful effects on humans.

When can I expect results?

The radiologist will review your scan data and the report will be sent to your doctor who will then discuss the scan results with you. Your doctor will interpret the results to you and this will enable him to monitor your liver health over time.

What other diagnostic procedures are there currently available to stage liver fibrosis?

- Liver biopsy is the gold standard
- MR elastography
- Serum Biomarker test

Limitations

The limitations of Fibroscan is

- Use on other organ besides liver
- Skin capsular distance of 3.5cm and more
- Evaluation of the liver may not be possible in the presence of ascites



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