Determination of the maximum load of the artificial loop ligaments of the ORTHOMED femoral cortex anchor ("ACF")

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Femoral fixation used for anterior cruciate ligament reconstruction by four-strand hamstring tendon autograft

The goal of the test is to **evaluate the force and the tensile extensibility during direct tensile tests**.

The knowledge of mechanical properties for each ligament let to valid the biomechanical performances of ligaments after insertion in the suitable implantation area.
The values inform about **the capability of ligament to perform its expected role.**
A direct tensile testing corresponds to a tensile testing where the displacement value and the extension value of artificial ligament are the same.

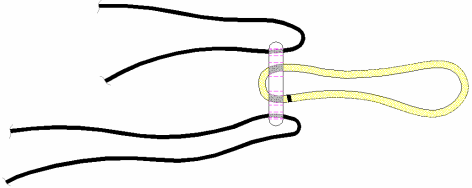
The test is performed according to the XP S 94-167-2 standard.

	Nom	**Fonction**	**Visa**	**Date**
Test protocol determination	S. ROLLIN	R&D Engineer		25/09/06
Test execution	S. ROLLIN	R&D Engineer		08/12/06
Test report preparation	S. ROLLIN	R&D Engineer		08/12/06
Test report approval	H. DUPUIS	Quality Manager		19/12/06

1. MATERIAL (SAMPLES)

-a- THE FEMORAL CORTEX ANCHOR (ACF)

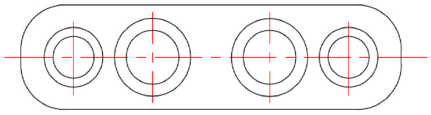
Fig 1. Scheme of femoral cortex anchor (ACF)



The ACF consists of a femoral plate with a polyester fabric loop run through the 2 inner holes of the plate.
A femoral cortex anchor is composed of 3 elements, a metallic plate with 4 aligned holes, an artificial ligament loop run through the 2 inner holes of the plate and two pull-wires through the 2 outer holes.

- **The metallic plate**

Fig 2. Scheme of metallic plate: 2 outer holes and 2 inner holes



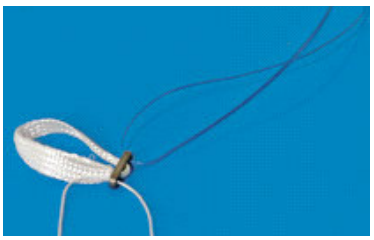
Characteristics of the plate: + TA6V ELI titanium alloy (ISO 5832-3 or ASTM F136)
+ plate width = 3.5 mm
+ plate is holed in 4 aligned places. Holes are symmetrical two by two, that is to say that the both outer holes are symmetrical and both inner holes are symmetrical.

↳ Both smaller outer holes let insertion of pull-wires. One pull-wire passes through each outer hole.

↳ Both inner holes let insertion of artificial ligament loop.

- **2 Pull-wires**

Fig 3. Femoral cortex anchor with 2 pull-wires, 800 mm length: one white and one coloured; the centre loop is made of polyester fabric.



A pull-wire is threaded through each of the 2 outer holes.

The artificial ligament is a braid composed of polyester, the polyethylene terephtalate (PET). Both extremities of braid overlap on some millimetres. The superposition of extremities is sewn.

The ACF has 2 pull-wires: one white and one coloured. They are both made of silicone polyester. Their physical and mechanical characteristics are identical:

Diameter: 0,8 mm
Tensile force: 264.78 N

Each pull-wire is folded into two by the femoral plate. Once inserted into plate, the tensile loads of the pull-wires threaded though the outer hole of the plate are 299.90 ± 21.79 N.

- **The artificial ligament loop in polyester, the polyethylene terephtalate (PET)**

The artificial ligament composed of PET is a braid. Mechanical data under tensile test given by furniture concerns ligament without exterior embrittlement:

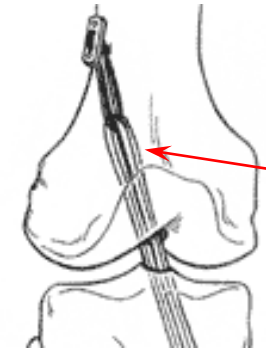
- Maximum load = 684 N
- Percentage of Elongation at rupture = 16,5%

The Orthomed society proposes many types of ACF fixation. These fixations are different because of artificial ligament loop length, once folded into two:

A.C.F.20 (textile loop, lg = 20 mm)
A.C.F.25 (textile loop, lg = 25 mm)
A.C.F.30 (textile loop, lg = 30 mm)
A.C.F.35 (textile loop, lg = 35 mm)
A.C.F.40 (textile loop, lg = 40 mm)

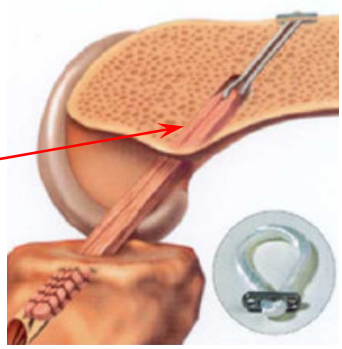
The width is the same for all A.C.F. textile loop.

The implanted ACF fixation is put on femoral trabecular bone. Its loop ligament passes though blind femoral channel and let to maintain the four-strand hamstring tendon autograft for the anterior cruciate ligament reconstruction.



Figs 4 & 5 Two views (right and left) of the femoral cortex anchor and its femoral fixation position

They show the blind tunnel into which the ACF is fitted to reach the cortex. The plate is fitted in a vertical position into a 4.5 or 5 mm bore and straightened at the level of the cortex.



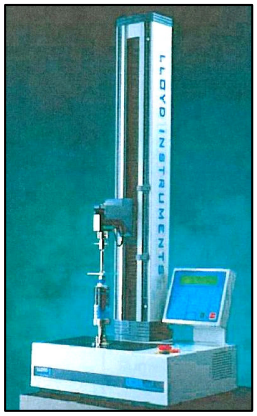
- 2 types of ACF15 have been tested:

Length of textile loop, folded into two, is always 15 mm.
One type of ACF15 has a loop composed of a braid 5,5 mm long.
The other type of ACF15 has a loop composed of a braid 6 mm long.

- All samples were tested after sterilisation: Certificate of irradiation AJ 89, the 29. November 2006.
- Shelf life of sterilisation: 5 years

-b- TRACTION AND COMPRESSION DEVICE WITH ITS NEXIGEN SOFTWARE

Fig 6 Tensile testing machine and NEXYGEN software



The tests were performed on an LRX Plus, single column, of 5kN capacity and has a force sensor of 2,5kN which let a great precision of results (0,5%). This device is a 0,5 class device, according to the NF EN ISO 7500-1 standard.
The last calibration was the 28th June 2005.

Its NEXYGEN software let to optimize the mechanical devise thanks to a schedule of testing and thanks to a fast lock-on of data.

The load measuring system exceeds the requirements of the following standards: NF EN ISO 7500-1: 2005
ASTM E4 et DIN 51221

2. TEST PROGRAM AND METHODS

Tests were carried out on sterile femoral trabecular anchor.
Tests were carrying out with device in constant speed of elongation. The followed NF EN ISO 7500-1 standard replaces the NF EN 10002-2 standard.
Tensile tests were carried out following the XP S 94-167-2 standard.

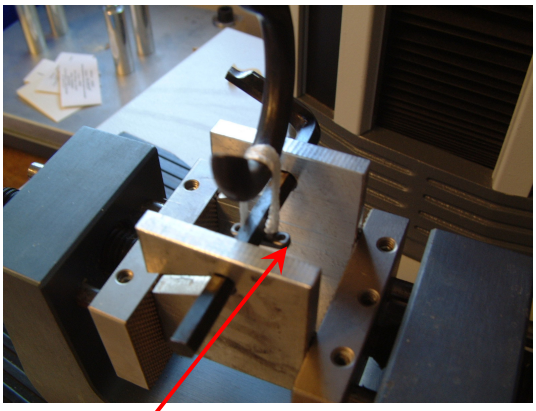
-a- PREPARATION OF SAMPLE BEFORE TESTING

- Before being tested, each ACF is dipped in physiological saline solution for 1 hour at least (20°C and 65% Relative Humidity), according to the NF EN 20139. It is needed for flexing artificial ligament fibres.

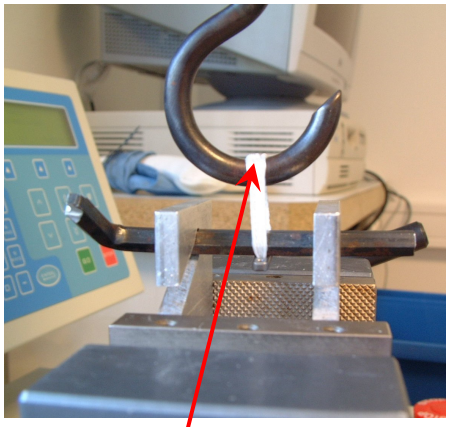
-b- POSITION OF SAMPLE IN MECHANICAL DEVICE

- Given that an ideal length of 100 mm between both grips of mechanical device is impossible to release, a 18 mm length is chosen (= length of tested sample). The distance between grips corresponds to loop artificial ligament folded into two and fitted into metallic plate.
- To be able to perform the tests, both extremities were fixed on device as shown in the following photography:

Figs 7 & 8 ORTHOMED ACF in the upper and lower grips for the tensile test



- Metallic plate is maintained horizontally by a hexagonal rod. The rod consists of the lower and static grip.



- Upper part of the loop is fixed by a hook on the upper grip.

-c- PROCESS OF DIRECT TENSILE TEST

- Preload = 2 N
- Speed elongation = 100 mm/min

The tests were performed at room temperature (about 25°C).

- **Maximal force evaluation**

This evaluation is obtained from **2 samples**.
Each sample is drawn until rupture. Maximal force is recorded.

- **Elongation evaluation at 75% of maximal force**

An average of maximal force is calculated from both maximal forces resulted from previous evaluation "Maximal tensile force evaluation".
The 3% and 75% is determined from the average of maximal force (The 3% of maximal force average does not exceed 5N).

3 samples are used for carrying out the elongation evaluation:

- Once located in the device fixation, one marker is marked on sample at the each grip.
- Sample is drawn until 3% of the maximal force average (without exceed 5N)
  - ↳ Note L0 distance which corresponds to the distance between both markers.
  - ↳ Read E0 extensibility on the force/extensibility curve, when force = 3% F_{max}.
- Sample is drawn until 75% of the maximal force average.
  - ↳ Note L1 distance which corresponds to the distance between both markers.
  - ↳ Read E1 extensibility on the force/extensibility curve, when force = 75% F_{max}.
- Sample is drawn until ultimate rupture.
  - ↳ Note F_{max} of sample.
  - ↳ Read E2 extensibility on the force/extensibility curve. E2 corresponds to the extensibility at F_{max}.

3. RESULTATS

The rupture takes place where the braid is sewn. The zone of sewing reinforces ligament strength whereas the sewing weakens the ligament at the level of this one: ligament fibres dissociate themselves then break.
This behaviour takes place every time. Any sample has failed.

-a- BREAK EVALUATION OF ACF 15 WITH A BRAID 5,5 CM LENGTH (**ACF 15-5,5**)

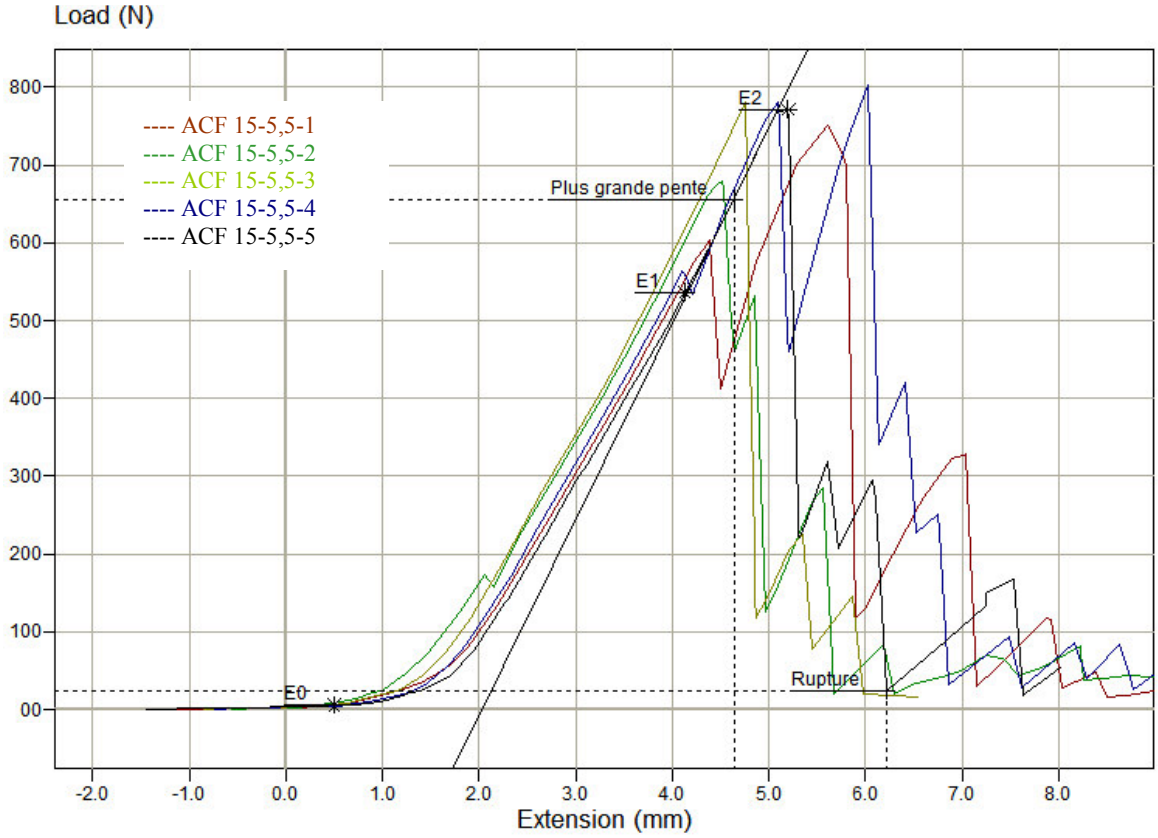
- **Maximal force evaluation**

Sample number	ACF 15-5,5-1	ACF 15-5,5-2	ACF 30
Maximal force, F_{max} (daN)	75,1	67,9	
Average of F_{max} (daN)	**71,5** ± 5,09		65,6 ± 5,58
3% of F_{max} average (daN)	2,14 > 0,5		1,48 > 0,5
75% of F_{max} average (daN)	53,6		49,2

Given that 3% of F_{max} average calculated exceeds 5N, I fix the first limit at 5N instead of 3% of F_{max} average for following the test: L0 will correspond to distance between both markers at 5N.

- **Elongation evaluation at 75% of maximal force**

Sample number	F_{max} (daN)	L0	E0	L1	E1	E2
ACF 15-5,5-3	78,1	16,27 mm	0,41 mm	19,66 mm	3,80 mm	4,75 mm
ACF 15-5,5-4	80,3	16,34 mm	0,60 mm	21,11 mm	5,38 mm	6,03 mm
ACF 15-5,5-5	77,1	16,94 mm	0,50 mm	20,57 mm	4,13 mm	5,20 mm



Figs 9 Force/elongation percentage curve of the 5 samples

- **Evaluation of Rigidity**

Sample number	ACF 15-5,5-1	ACF 15-5,5-2	ACF 15-5,5-3	ACF 15-5,5-4	ACF 15-5,5-5	**Average**
Rigidity (daN/mm)	29,9	24,8	26,4	30,9	25,1	**27,4 ± 2,8**

-b- BREAK EVALUATION OF ACF 15 WITH A BRAID 6,0 CM LENGTH (**ACF 15-6,0**)

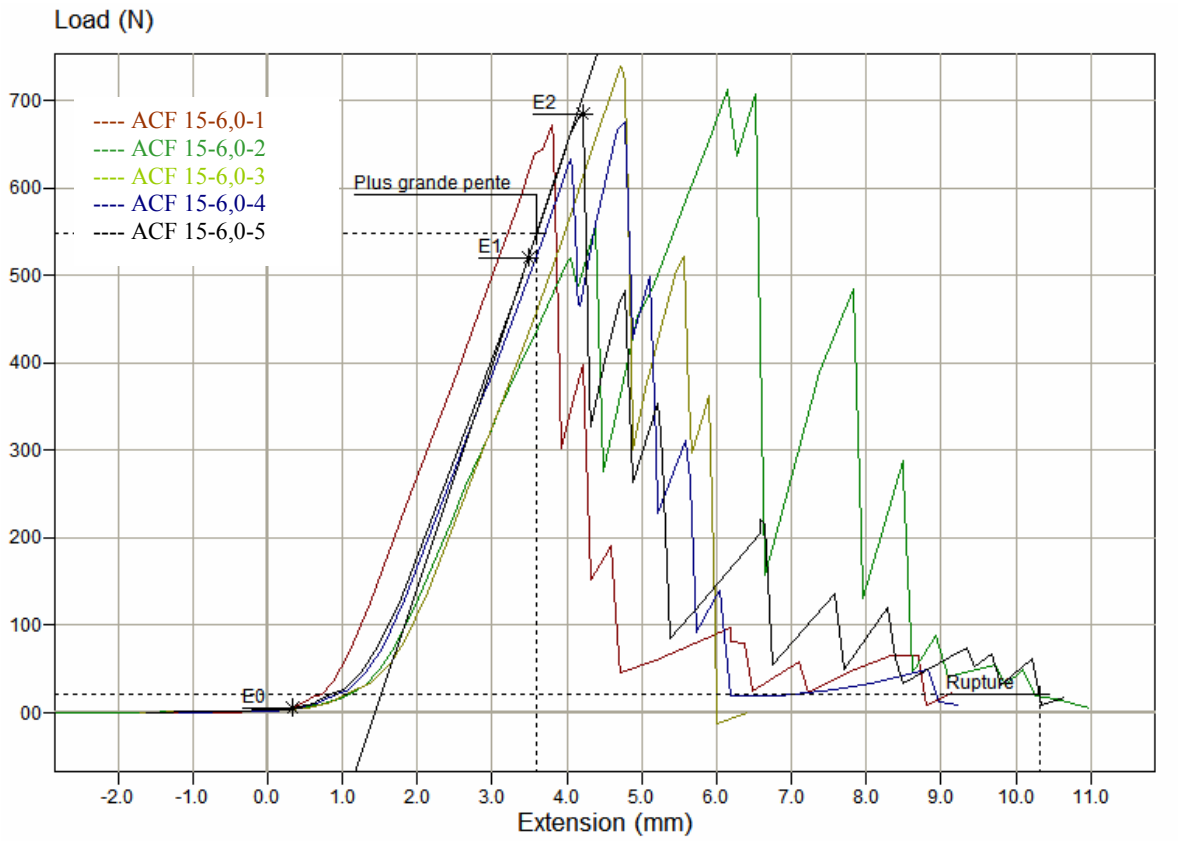
- **Maximal force evaluation**

Sample number	ACF 15-6,0-1	ACF 15-6,0-2	ACF 30
Maximal force, F_{max} (daN)	67,2	71,3	
Average of F_{max} (daN)	**69,2** ± 2,90		65,6 ± 5,58
3% of F_{max} average (daN)	2,07 > 0,5		1,48 > 0,5
75% of F_{max} average (daN)	51,9		49,2

Given that 3% of F_{max} average calculated exceeds 5N, I fix the first limit at 5N instead of 3% of F_{max} average for following the test: L0 will correspond to distance between both markers at 5N.

- **Elongation evaluation at 75% of maximal force**

Sample number	F_{max} (daN)	L0	E0	L1	E1	E2
ACF 15-6,0-3	73,9	17,2 mm	0,45 mm	20,55 mm	3,84 mm	4,71 mm
ACF 15-6,0-4	67,5	16,55 mm	0,37 mm	20,47 mm	4,29 mm	4,77 mm
ACF 15-6,0-5	68,4	16,94 mm	0,33 mm	20,10 mm	3,49 mm	4,21 mm



Figs 9 Force/elongation percentage curve of the 5 samples

- **Evaluation of Rigidity**

Sample number	ACF 15-6,0-1	ACF 15-6,0-2	ACF 15-6,0-3	ACF 15-6,0-4	ACF 15-6,0-5	**Average**
Rigidity (daN/mm)	25,5	22,8	26,1	24,2	25,3	**24,8 ± 1,3**

CALCULATIONS AND EXPRESSION OF RESULTS

Sample number	Elongation at 75% of F_{max} average: $100 \times \frac{(L1 - L0)}{L0}$	Elongation at F_{max}: Elongation at 75% of F_{max} average $\times \frac{(E2 - E0)}{(E1 - E0)}$
ACF 15-5,5-3	20,8 %	26,7 %
ACF 15-5,5-4	29,2 %	33,2 %
ACF 15-5,5-5	21,4 %	27,7 %
ACF 15-5,5 Average	**23,8 % ± 4,7 %**	**29,2 % ± 3,5 %**
ACF 15-6,0-3	19,5 %	24,5 %
ACF 15-6,0-4	23,7 %	26,6 %
ACF 15-6,0-5	18,7 %	22,9 %
ACF 15-6,0 Average	**20,6 % ± 2,7 %**	**24,7 % ± 1,9 %**
ACF 30 Average	**16,9 % ± 1,8 %**	**21 % ± 2,6 %**

OBSERVATIONS

- Given that each ACF model shows the same width and the same sewing type, all ACF models have the same mechanical properties.
- Knowing that the anterior cruciate ligament (ACL) is stressing between 150N and 500 N during a daily activity, fixation used the reconstruction of ACL will support the same stress at least (500N) to let an intensive rehabilitation of knee. So ACF 15-5,5 and ACF 15-6,0 satisfy a such rehabilitation:

(F_{max} average of ACF15-5,5 = **71,5** ± 5,09 daN ; F_{max} average of ACF15-6,0 = **69,2** ± 2,90)

- In comparison with ACF 30 samples, values obtained with both ACF 15 samples are greater. Nevertheless difference is not important and values are of the same order of magnitude.
- Contrary to ACF 15-5,5 samples, ACF 15-6,0 samples show greater elongation, at 75 of F_{max} average and at F_{max} too. Moreover Rigidity of ACF 15-5,5 samples is more elevated than those of ACF 15-6,0 samples. Nevertheless values are rather similar.

Given the close values of results, it would be better to choose sample with more elevated mechanical properties.

CONCLUSION

To conclude, the present study shows that the all dimensions of ACF fixation are suitable for ACL reconstruction fixation.

Comparison between tensile properties of both ACF 15 (braid 5,5 cm length and braid 6 cm length) leads to propose the ACF 15 with a braid 5,5 cm length as the more suitable fixation.

Elongation at 75% of F_{max} average: 23,8 % ± 4,7 %

Elongation at F_{max}: 29,2 % ± 3,5 %

Average of F_{max}: 71,5 ± 5,09 daN