CLINICAL EVALUATION OF TRADITIONAL TRANSOSSEOUS AND FISH-FIT MD ROTATOR CUFF REPAIR

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Introduction

The goal of rotator cuff repair is to achieve high initial fixation strength, minimize gap formation restoring a wide foot-print, maintain mechanical stability under cyclic loading and optimize the biology of tendon-bone healing .

Several works[1,2] have shown how rotator cuff tears repaired by a transosseous approach are able to obtain a better functional reconstruction and a relevant pain reduction compared to others repairing ways. For many years, however, this technique was restricted only to open or mini-open surgery because of its difficulty. Nowadays, thanks to the quickly technological evolution occurred in the last years in this field, it is possible to perform a transosseous repair also in arthroscopic surgery, joining the effectiveness of the technique in the recovering of the shoulder functionality and in the pain reduction with the rate and the safety of the surgical procedure.

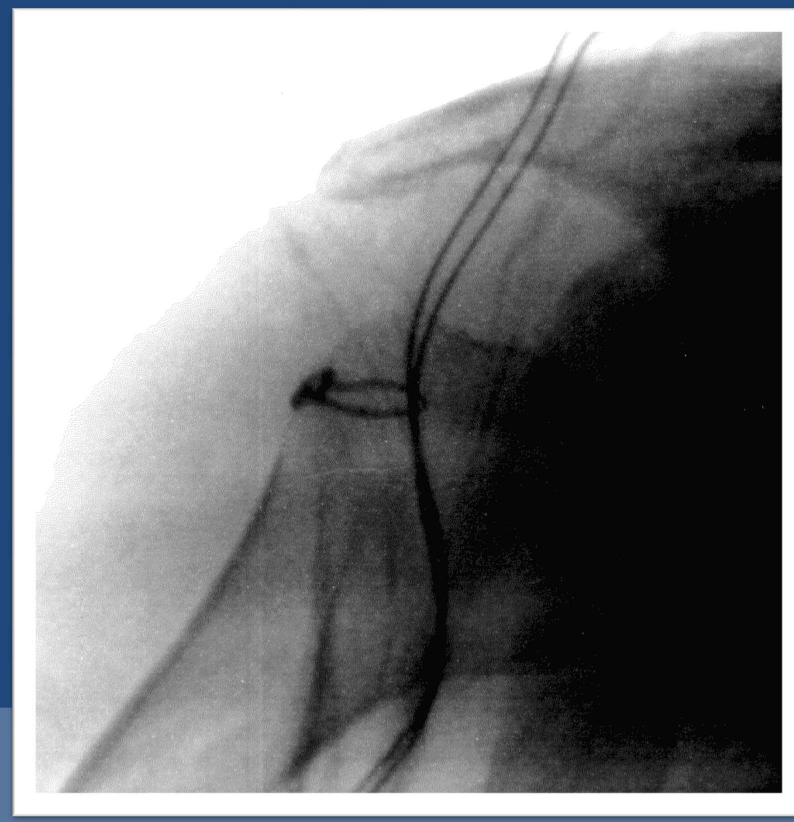

Figure 1: Rx image of an implanted Fish-Fit MD device.

A mid-step: transosseous equivalent, is it?

The first step to approach the arthroscopic transosseous technique in rotator cuff repair was the called, transosseous equivalent technique. This approach, that involves the construction of a medial row in the foot-print region, and a lateral row on the great tuberosity rim, attempts to replace the transosseous technique, making the arthroscopic procedure easier, but without achieving the same biomechanical behavior for two main reasons:

- interface between suture and tendon is critical because force isn't dissipate along all suture loop,
- possibility of device migration due to weak bone quality.

The transosseous way: advantages and disadvantages of the classic approach

ADVANTAGES	DISADVANTAGES
• Excellent outcome data[3]	• Difficult to perform
• Low cost	• Time to perform
• Wide foot-print[4]	• Suture-bone cut effect
• Good contact pressure[4]	
• No device migration[5]	

The solution: Fish-Fit MD

Fish-Fit MD is a suture platform for the treatment of rotator cuff tears developed to overcome the traditional transosseous approach deficiencies in arthroscopy. The device has a slotted body designed to manage one to four inner sutures (more are also possible), his shape was created to maximize the resistance to pull-out effect and to prevent suture-bone interaction. The head provides high stability to the system due to the external sutures that achieve a force equilibrium.

One of the main device features refers to his placement in a region with a good bone quality, located about 15/20mm distally to the great tuberosity rim. This capability allows to obtain a significant decrease in the possibility of repairing failure due to suture bone cut effect. Furthermore the device behaves as a bridge, improving the way suture impact over bone. To overcome the traditional difficulties related to the transosseous arthroscopic repair procedure, the device and the required sutures can be placed through specific surgical instrumentations that allow to perform a guided and repeatable procedure saving operative time.

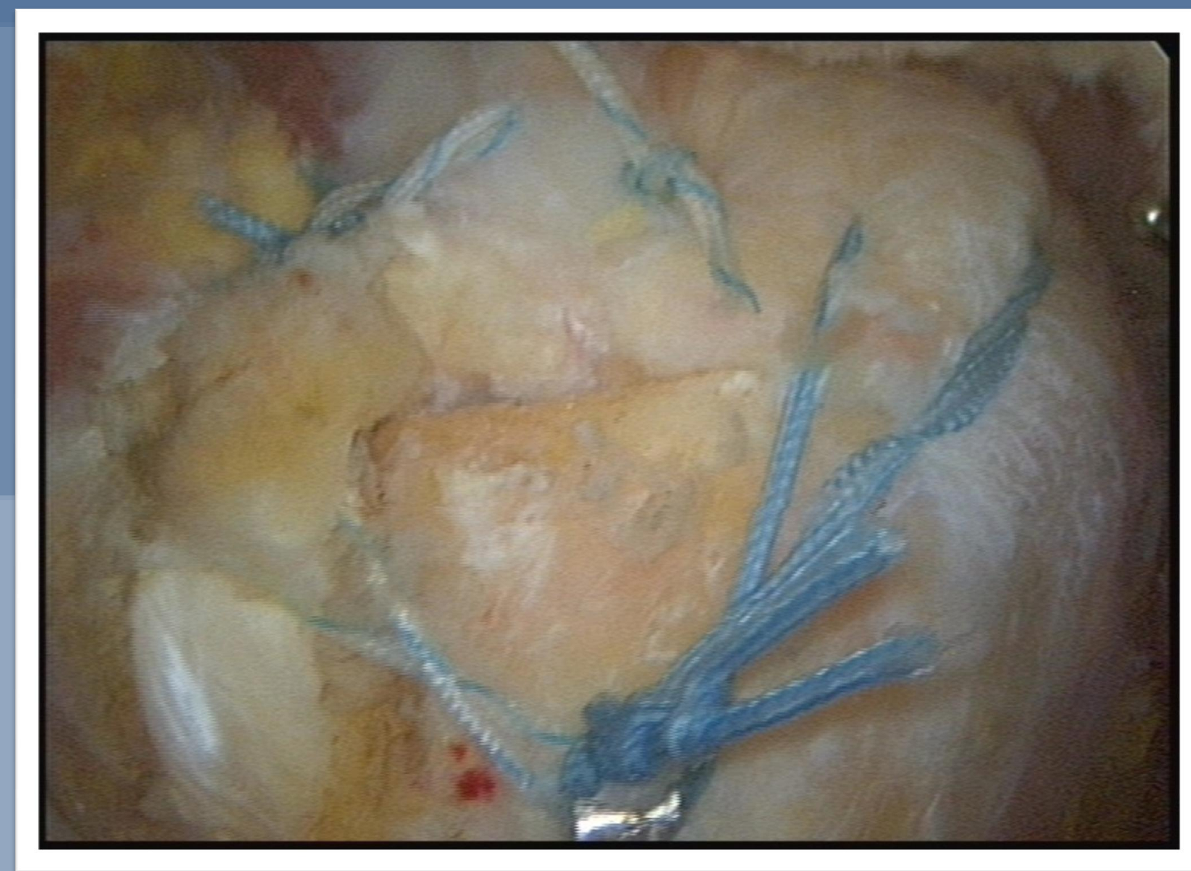

Figure 2: Arthroscopic view of rotator cuff repair performed with Fish-Fit MD .

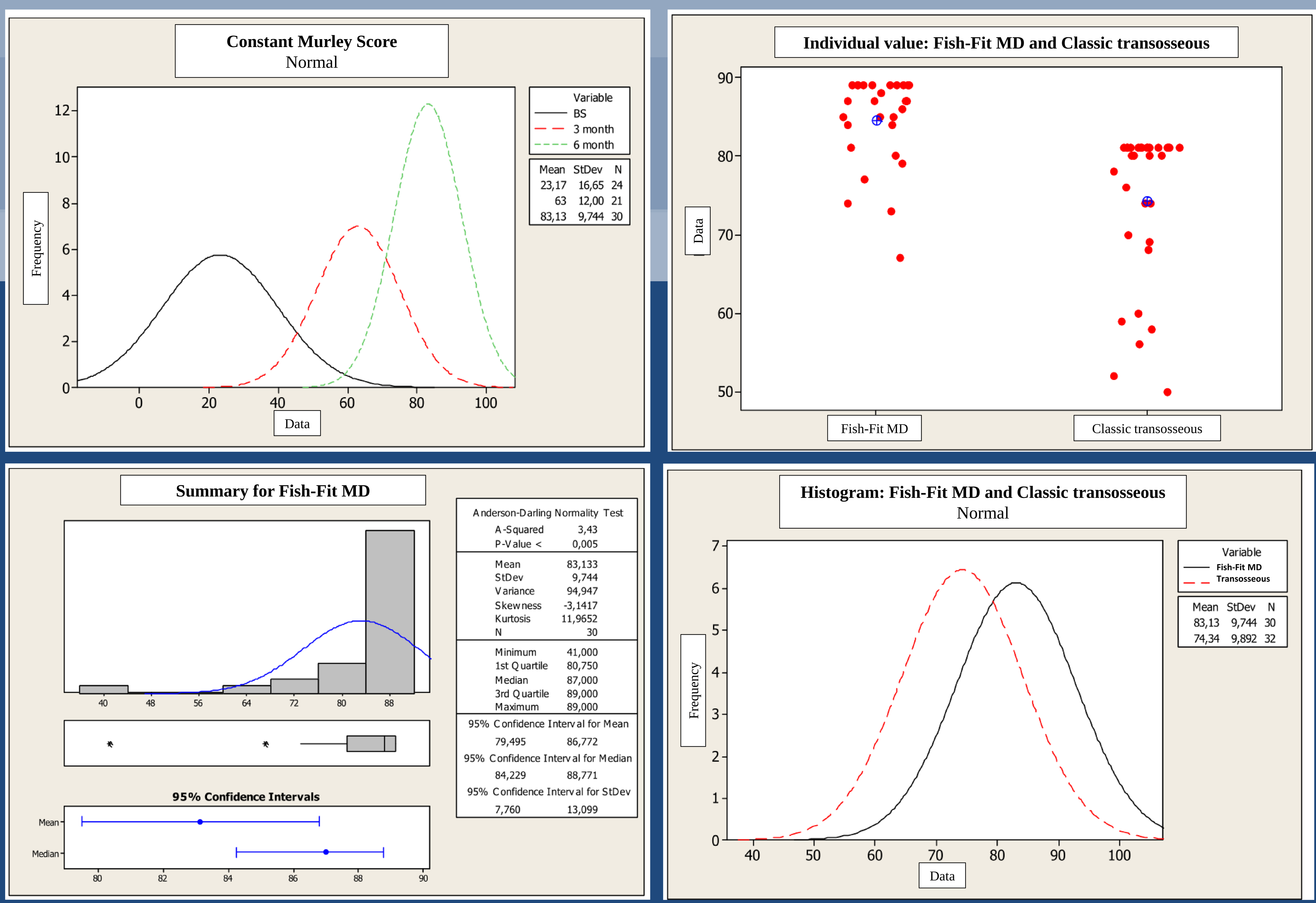

Figure 3: Fish-Fit MD Constant-Murley score normal distribution before surgery and at 3 and 6 months (top-left); Comparison of Constant-Murley score distribution between Fish-Fit MD and Classic transosseous (top-right); Statistical data of Fish-Fit MD clinical outcomes (bottom-left); Comparison of Constant-Murley score normal distribution between Fish-Fit MD and Classic transosseous (bottom-right).

Classic transosseous Vs. Fish-it MD: clinical outcome

Thirty patients were found suitable to be treated with Fish-Fit MD device. All 30 patients were available for follow-up at a mean of 6,4 months (range, 3 to 12 months). There were 16 men and 14 women, with a mean age of 63,6 years (range, 41 to 77 years). All patients had suturable massive tears (wider than 3 cm) that affected one or more tendons. The repair configuration involved the use of 1 or 2 (one patient) devices with only transosseous sutures for the medial row and external sutures for the lateral row. After surgery the upper limb was immobilized for 20 days, allowing only shoulder and elbow passive mobilization. The patient were reviewed after 3, 6 and 12 months for assessment and evaluation throw Constant-Murley Shoulder Outcome Score, RX and RMN imaging.

The patients shown a mean Constant-Murley Score of 23,2 (range, 12 to 71) pre-surgery. After 3 months the mean score was 63,0 (range, 43 to 82), the strength tests were performed with 2 kg weights and corresponding reduced score. After 6 months the mean score achieved from patients was 83,1 (range, 41 to 89). Finally, after 12 months, the mean score related to 10 patients was 86,9 (range, 73 to 89).

The study compared this data with results obtained from thirty-two patients with massive rotator cuff tears treated with a classic transosseous approach. All patients were available for a 6 months follow-up. There were 17 men and 15 women, with a mean age of 61,2 years (range, 36 to 75 years).

CONCLUSIONS

The compared study between rotator cuff tears repaired with Fish-Fit MD device and through a classic transosseous approach, shows at 6 months a clinical outcome data (Figure 3) that indicates a statistically significant results improvement in patients treated Fish-Fit MD device (P<0,005), furthermore no RX imaging revealed device migration in all patients treated with it.

Fish-Fit MD: flexible in repair

Among Fish-Fit MD features, one of the most distinctive, is the opportunity to perform a wide and personalized range of repairs. This capability is due to his structure, that allows to use it as a suture platform with a variable number of internal and external sutures which can be arranged in many configurations. As mentioned, the device can manage up to four internal sutures and two external, which can be organized according to tendon tears and to preferences in the surgical procedure (Figure 4).

To perform a more freely repair, when massive tears were found, surgical instrumentations allow to realize multiple medial holes, 2-3mm in diameter, through a single 3mm lateral hole, allowing to obtain a more suitable sutures distribution. Seldom, when a rotator cuff reconstruction is needed, it is also possible to use two implanted devices, in such a way to manage a higher number of sutures.

Figure 4: RCR through Fish-Fit MD with two internal sutures for tendon to bone compression and two external sutures for pulling the tendon (first); : RCR with Fish-Fit MD and three internal sutures that close the suture loops passing through the eyelet on the device (second); RCR with Fish-Fit MD where the three internal sutures were fixed with a knot to the device head (third); RCR of a massive tear with Fish-Fit MD and four internal sutures (fourth).

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