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ORIGINAL STUDY

High incidence of intraoperative anchorage failure in FasT-fix™ all inside meniscal suturing device

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The aim of this study was to assess the incidence of intraoperative failure of the FasT-fix™ (Smith & Nephew, Andover, USA) device for all-inside meniscal repair and to investigate any underlying factors. Searching retrospectively the hospital databases and patient files, we collected 78 cases, totalling 61 successes and 17 failures. Of a total of 190 FasT-fix anchors, 22 failed (a calculated incidence of 11.6%), either by anchorage slippage through the capsule during tightening or by failure of anchor deployment.

Keywords : meniscus ; arthroscopic meniscal repair ; all-inside ; FasT-fix.

INTRODUCTION

In recent years, treatment of meniscal lesions has evolved rapidly. Partly due to the long-term disadvantages of (partial) meniscectomy (*3,5,9*), more conservative techniques have gathered popularity (*6*). Less invasive methods have the benefit of a decreased risk of neurovascular injury and articular cartilage excoriation/abrasion. Besides the established outside-in and inside-out procedures, many all-inside suturing devices have been marketed. These techniques of arthroscopic surgery have markedly improved the outcome of meniscal trauma, compared to more traditional suturing (*4*). Four generations of meniscal repair techniques can be defined. The first two generations were open procedures and arthroscopically assisted inside-out or outside-in techniques. A third generation introduced devices, specifically designed for meniscus tear applications. The first devices used were simple rigid structures that fixated both edges of a tear-site by pulling them together using barbs or threads. Third generation devices experimented with bioabsorbable materials, but lacked the ability to adjust compression and tension across a tear site. Because of the relatively poor results and complications from these crude devices, a fourth generation of techniques was developed : all-inside devices using sutures to fixate meniscal tears. By means of a set of two absorbable implants anchors connected via a pre-made suture and sliding knot, compression of the tear is achieved. These flexible, suture-based applications overcome the limitations of the third-generation devices by allowing variable compression

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and tensioning (*2,10*). Apart from their use in tear repair, these devices are also used in meniscal transplantation, where they form an alternative to traditional suturing in fixating the allograft or scaffold in the knee joint.

One of the more popular fourth-generation devices is the FasT-fix™ All-Inside Meniscal Repair Suture System (Smith & Nephew, Andover, USA). Three versions are available ; a straight needle delivery system and both a -22° and +22° angled curved needle. The latter is considered to be the most practical and is therefore most often used. The device consists of two non-resorbable suture anchors, preloaded in the delivery system. These implants are pierced through both sides of the lesion and the meniscocapsular layer. Before application, the surgeon has to ensure that the anchor is fully loaded in the delivery device to prevent disengaging or dislocation of the implant. The anchors are slid into place and remain fixated outside the capsule when applying a slight tension to the suture thread. Excessive penetration can be prevented by using a depth gauge before puncturing the meniscal and capsular tissue. Subsequent tightening of the suture by a prefabricated sliding knot mechanism by means of a specially designed knot pusher/suture cutter, allows compression of the tear-site. In this way it closes and stabilizes the lesion (*7*).

This study aims to assess the incidence of failure of these devices, including failure of deployment of the first and/or second anchor, disengaging of the anchor when applying light tension, premature deployment of the anchors and difficulties with penetrating the meniscal tissue (*8*). These practical difficulties using the FasT-fix™ were experienced repeatedly during numerous interventions, and forced surgeons to take extra steps necessary to remove the failed device and to ensure that a decent suture was placed, while preventing any iatrogenic damage to meniscus or cartilage. Malfunctioning of the device thus complicated the course of otherwise routine interventions (Fig. 1).

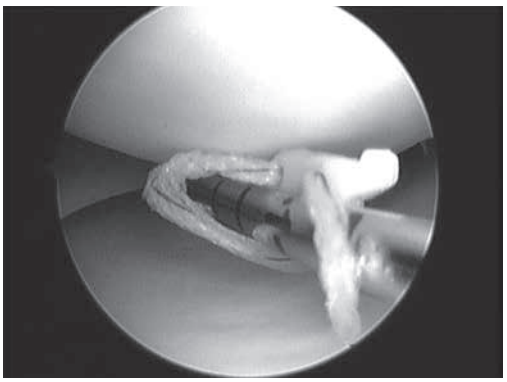

Fig. 1. — Intraoperative arthroscopic image of failure to deploy a FasT-fix™ anchor from the capsule. (single field extracted from a frame with interlaced signal).

MATERIAL AND METHODS

Based upon our Department's database, 208 patients who had had meniscus repair surgery between 20.08.2003 and 31.03.2013 were selected, after excluding 13 files either because they concerned a different indication or lacked certain key data. Another 130 patients were excluded because other procedures, such as other all-inside devices, inside-out, outside-in or traditional suture meniscal repair, were used instead of the FasT-fix™ device. All 78 procedures using the FasT-fix™ device for meniscal suturing by Smith & Nephew (Andover, USA) were checked for intraoperative device failure – either because of anchor slippage through the capsule during tightening or because of a complete failure of anchor deployment. As such, 17 patients were regarded as failures. In 61 cases the device did not fail, these were defined as successes (Fig. 2).

After rigorously analysing all patient files in the failed group, cases were divided into separate subgroups, depending on the indication in which the device was used. As such, two sets of cases were formed : groups A (9 cases) and B (8 cases), respectively tears in a native meniscus and meniscal transplantations. The same differentiation was applied to the 61 successes.

Each failure was thoroughly analysed for various factors. In addition to patient-related factors such as sex and age at procedure, indication-related factors such as the side and meniscus that was treated, were investigated. Depending on the indication – tear or transplant – other factors were added. In group A (tears), a systematic description of the lesion was defined using the ISAKOS classification. This method of classification designed by the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS) was recently tested for international inter-observer reliability and was proven to be superior to other ways of defining meniscal tears. The classification form consists of nine

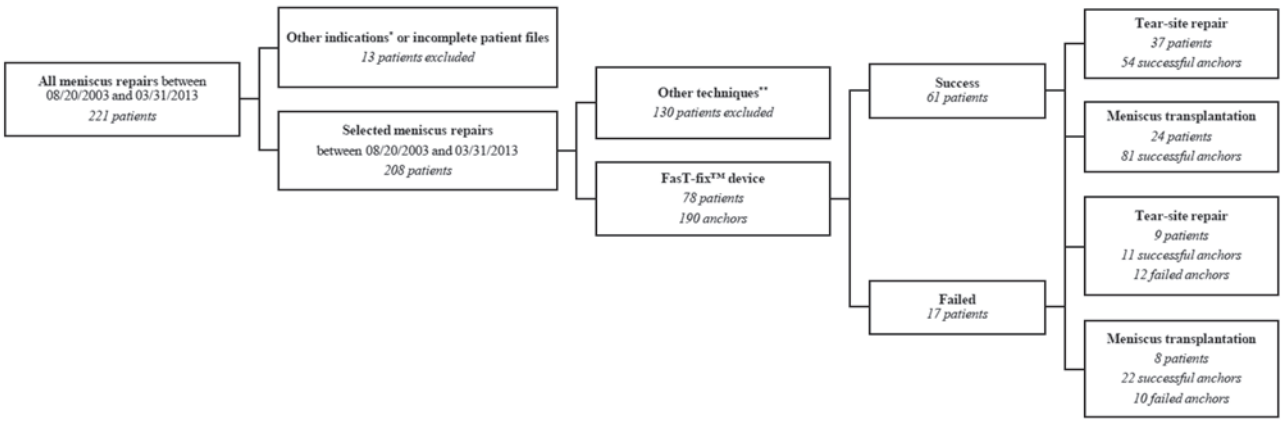

Fig. 2. — Selection algorithm

items that describe type, location, length, orientation, etc (*1*). In group B (transplants), we differentiated between allograft or scaffold transplantations.

RESULTS

In 61 out of the 78 cases in which the FasT-fix™ device was used, no technical problems were encountered. In 17 cases – 21.8% of all patients – however, the device malfunctioned. Both the failures and the successes were analysed for the indication of the procedure – either repair of a tear-site or usage in a meniscus transplantation. Among the 61 successes, there were 37 tears and 24 transplantations. The 17 failures were divided into 9 tears and 8 transplants. Fifty-nine percent (46) of all FasT-fix™ procedures were tear-repairs, as 41.0% (32) were in meniscus transplantations.

According to the indication and clinical situation, some procedures required the use of more than 1 FasT-fix™ device per patient ; this explains the discrepancy between the number of patients and the number of devices used. In total, 190 FasT-fix™ devices were used. When looking at the distribution of the two subgroups, we can see that in general more devices were used in transplantation-procedures : 77 devices used in tear repairs as opposed to 113 in transplantions. We calculated that 11.6% (22) of all devices used had malfunctioned intraoperatively. These 22 device failures were clustered in 17 patients with intraoperative failure, averaging at a little over 1 (1.29) device failure per patient in this group.

Taking a closer look at the failure rates in our subgroups, we see a relatively higher failure rate in tear repair setting (54.5% of all failures) than in transplantation setting (45.5% of all failures). This difference is confirmed in the success rates in these categories : 38.7% success in tears as opposed to 61.3% in transplantations.

Table I shows the patient-related and pathology-related factors for the two failure subgroups.

DISCUSSION

The results of this study confirm our observations of a high incidence of intraoperative failure of the FasT-fix™ device. Malfunctioning of the device occurred either by anchorage slippage through the capsule during tightening or by a complete failure of anchor deployment. A possible explanation for these findings could be a design flaw. Experience suggests that the anchors sometimes do not fully deploy – even when correctly preloaded according to the manufacturer's instructions – and therefore are not able to lock behind the capsule. Others believe that a longer shelf-age of the device makes it more prone to failure. Furthermore, patient-dependent factors may promote intraoperative malfunction. As such, poor quality of meniscal tissue may cause dislocation of the anchors because of a lack of grip.

Table I. — Patient demographics and pathology related data. *The meniscus was divided into 3 zones in order to assess the rim width: < 3mm, 3 to < 5 mm and > 5 mm to the exterior edge of the meniscus. †One patient underwent procedure on both knee joints. ‡One patient underwent procedure on both menisci in one knee joint

	Patient demographics			Pathology related data						
	Patients (n)	Average age (years)	Gender	Side	Meniscus					
Group A (Tear)						ISAKOS classification				
						Zone*	Location	Type	Tissue quality	Average length
	9	28 [17-44]	4 Male 5 Female	5 Left 4 Right	2 Lateral 7 Medial	7 Zone 1 2 Zone 2	4 Posterior 3 Posterior to Mid-body 2 Posterior to anterior	6 Longitudinal 2 Bucket handle 1 Complex	All non-degenerative	29.7 mm
Group B (Transplant)						Transplant				
	8	22 [16-28]	2 Male 6 Female	5 left 4 right†	6 Lateral 3 Medial‡	5 Allograft 4 Bio-scaffold				

The higher failure rates in tear repairs could be explained by a defective quality of meniscal tissue, due to trauma, in some cases. This factor is overcome in transplantations, where good quality tissue from selected allografts or synthetic materials as in bio-scaffolds are used.

Among the patient and indication dependent factors, none was found to have a significant impact on the incidence of intraoperative failure of the FasT-fix™ device. It is possible however, that this is a consequence of the limited size of the clinical material in this study, and more significant conclusions may be drawn from further investigation in following research.

To the best of our knowledge, this research paper is the first one to report on this issue of intraoperative failure of the FasT-fix™ device. Smith & Nephew, as well as other companies, have addressed this complication and have developed new devices for all-inside meniscal suturing such as the Ultra FasT-fix™ and FasT-fix 360™ (both Smith & Nephew, Andover, USA). These versions feature certain modifications which supposedly lower the intraoperative failure rate as described in this paper. Therefore, several institutions already changed their policy in this setting and prefer using the newer versions in the majority of cases, although more research is needed to prove the superiority of this next generation of meniscal suture devices.

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