Incidence and Mode of Deployment Failure of the Fast-Fix 360™ Meniscal Repair Device

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Research article

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Abstract

Background Meniscal repair device deployment failure is a recognised complication of all-inside meniscal repair with subsequent risk of patient harm. The Fast-Fix device has undergone design changes to reduce deployment failure since its introduction in 2001.

Purpose The purpose of this study was to assess the incidence and mechanism of intra-operative deployment failure of the 3 rd generation Fast-fix 360™ (Smith & Nephew, Andover, USA) device.

Method Data was prospectively collected for 106 consecutive all-inside meniscal repairs undertaken with the Fast-fix 360™ device. Patient demographics, mechanism of failure, site and type of repair were recorded.

Results 20 deployment failures occurred in 423 Fast-fix 360™ deployments, an incidence of 4.72%. Deployment failure occurred in 19 of 109 patients an incidence of 17.43%. Six different failure mechanisms occurred; anchor exiting device without trigger being initiated, anchors not holding in meniscus, both anchors simultaneously exiting device and braided suture failing. The most common failure mechanism was failure of the second anchor not holding in the meniscus. Average cost of device failure was $75 per patient.

Conclusion Despite design modification, deployment failure still occurs with similar modes top to the original design.

Introduction

Preservation of the torn meniscus is being increasingly performed, with the majority undertaken using all-inside repair, despite inside-out repair remaining the gold standard. [1] [2] [3] [4] [5]. The advantages of all-inside repairs are less risk of neurovascular injury, no separate incision, less operative time and less technical difficulties. The main disadvantages to all-inside are higher cost, possibly lower healing rates and chondral damage from devices.

All-inside repairs are typically undertaken with specific all-inside devices such as darts or arrows that cross the meniscal tear site and afford apposition and or compression of the tear by barbs or threads on the device, or suture anchor devices that deploy two small anchors attached to a suture allowing compression and closure of the meniscal tear [3].

One of the most common all inside suture/anchor device is the Fast-fix™ Meniscal Repair System by Smith & Nephew, introduced in 2001 with subsequent modifications to improve deployment consisting of a pre-packaged suture/anchor device with-in a single use cannulated needle delivery device.

This original design had a deployment failure rate of 11.6%, either by anchorage slippage through the capsule during tightening or by failure of anchor deployment [6]. The deployment failure rate of the most current design, the Fast-fix 360™, remains uncertain.

The purpose of this study is to determine the deployment failure rate of the Fast-fix 360™ during meniscus repair.

Materials And Method

The aim of the study was to identify the incidence and mode of deployment failure of the Fast-Fix 360™ meniscal repair device in clinical practice.

Data was prospectively collected on the use of the Fast-Fix 360™ suture device for all-inside meniscal repairs over a period of 9 months in the calendar year 2016 at Kawana Private Hospital, Queensland, Australia. There were no exclusions.

All cases were performed by a single Fellowship trained surgeon experienced in the use of the Fast-fix 360™ suture device.

All procedures were via a 2 portal arthroscopy technique utilising anteromedial and anterolateral portals. An all-inside meniscal repair using the Fast-fix 360™ was performed for tears in the posterior third of either meniscus. If the meniscal tear extended to the middle third or anterior third such as a bucket handle tear then the posterior third would be repaired with the Fast-Fix 360™ suture device with the middle third being repaired with inside-out sutures and occasionally outside-in sutures were used if the tear extended into the anterior third of the meniscus.

Medial meniscal repairs were undertaken with the knee positioned in slight flexion with a valgus stress applied and rotation controlled by an assistant. Lateral meniscal repairs were undertaken with the knee in the figure-four position. The meniscal sutures were deployed from the portal which would afford the most perpendicular approach to the meniscus. Commonly both portals would be utilized for each repair with flexion changing to allow access for each deployment.

After tear apposition, Anchor 1 is placed in the capsule of the least mobile meniscus portion using the device needle of the delivery device and deployed by the trigger mechanism. The meniscus is then penetrated a second time in close proximity to Anchor 1 placing the sutures across the tear, again deploying the anchor posterior to the capsule via the trigger mechanism. The delivery device is then removed from the joint leaving the 2 deployed anchors, knot and suture within the joint. The suture's one way, sliding knot, is then tensioned affording compression to the tear, and the suture tail is then cut. Further devices are placed depending on tear pattern and size. No device delivery needles were deliberately bent before suture deployment as this can increase deployment failure. Repair device needles were placed as perpendicular to the meniscal axial plane as possible to avoid deployment failure. If deployment failure occurred the anchors and sutures were removed and another device was inserted.

The procedures were performed in a single operating theatre with the same theatre staff collecting data on a dedicated implant recording sheet which was a component of the operative count system. Deployment failure was defined as any failure to deploy both anchors into the meniscus and slide the knot onto the meniscus to compress the meniscal tear.

The site and mode of deployment failure, patient demographics, concomitant surgery were recorded as well as side and morphology of meniscal tear. Any visible injury due to deployment failure was recorded. The recorded data sets were analyzed using Student's t-test to determine whether one particular group was more prone to failure than others. A t-value greater than 1 was determined to be indicative of a possible correlation between a particular group and failure rate.

Device costs were obtained from the Australian Federal Department of Health' Prosthesis List.

Table 1: Patient Demographics

Demographic	
Number of Patients	109
Male	74 (68%)
Female	35 (32%)
Age range	(12-70)
Average age	30.45 years

Table 2: Types of Surgeries

Types of Surgeries	Number of surgeries	Percentage of Total Surgeries (%)
ACL reconstructions Medial meniscal repair	21	19
ACL reconstructions Lateral meniscal repair	24	22
ACL reconstructions Medial and Lateral meniscal repair	17	16
Medial meniscal repair	28	26
Lateral meniscal repair	16	15
Medial and Lateral meniscal repair	1	1
Posterolateral corner repair +lateral meniscal repair	2	2
Average number of Fast-Fix 360™ per meniscus	3.3	

Table 3: Classification of Meniscal Tears

Meniscal Tear	Number of Occurrences (Lateral)	Number of Occurrences (Medial)	Average size of tear (mm)
Radial	4(3%)	0	5
Ramp	0	4(3%)	10
Flap/Parrot Beak	2(1.5%)	0	8
Root Tear	13(10%)	11(9%)	4
Bucket Handle	11(9%)	10(8%)	18
Horizontal Cleavage	0	0	12
Longitudinal Tears	15(12%)	39(31%)	12
Complex Tears	15(12%)	2(1.5%)	10
Degenerate Tears	0	0	0
Total Meniscal Tears	60(48%)	66(52%)	

Results

126 all-inside meniscal repaired were undertaken with 423 Fast-fix 360™ Meniscal Repair suture devices used (mean 3.3). Tables 1-3 express the range of the study, with Table 1 showing the ages and genders of the patients, Table 2 indicating which surgeries were included in the study, and Table 3 classifying the tears which were operated on throughout the study. 20 deployment failures were recorded in 19 cases, a rate of 4.7% of all suture deployments and 17.4% of all cases (refer to Table 4 for the demographics of said failures). The failure group were on average younger than the total group however Student's T-test value of 0.358 did not show a correlation with age and failure. However within the failure group age over 40years showed a significant correlation with failure Student's T-test value of 6.39. The failure group comprised a higher proportion of males than females with Student's t-test value of 2.02 indicating there may be a correlation between gender and failure rate).The failure group used a slightly lower number of Fast-Fix 360™ suture devices per surgery then the total group. The most common site of failure was at Anchor 2 (Table 5), while the commonest mode of failure was failure of anchor to exit device (Table 6).

Deployment failure was most common during an ACL reconstruction with medial meniscal repair (37% in failures vs 19% in total group) (see Table 7). A Student's t-test comparing ACL reconstruction medial meniscal repair failures to the total failures revealed a value of 1.58 indicating this type of surgery may be more prone to failure than others. ACL reconstruction with medial meniscal failure surgery was followed by Arthroscopic lateral meniscal repair in number of failures (26% in failure group vs 15% in total group). When comparing Arthroscopic lateral meniscal repair failures with total failures, a t-value of 1.14 was found and indicates that this type of surgery maybe more prone to failure.

The most common tear pattern in deployment failures were longitudinal tears for medial meniscal tears (42% in failures vs 32% in total group) (shown in Table 8). A Student's t-test value of 0.68 was found when comparing longitudinal tear failures to total meniscal failures. This t-value indicating low correlation between longitudinal tears and failures during medial repair surgeries. Longitudinal medial meniscal tears were the most common type of tear repairs in both the failure group and total groups.

For lateral meniscal repairs, failures during complex tear repairs were the most prevalent (37% in failures 12% in total group). Comparing these two groups (complex tear failures and total lateral meniscal repair failures) found a Student's t-test value of 2.31. This t-value is large, indicating that complex tears are likely to be more prone to failure during lateral meniscal repairs. This is also seen in table 8 as almost all the lateral repair failures occur with a complex tear.

Table 4: Patient Demographics Deployment Failure

Male	16(80%)
Female	4 (20%)
Age range	14-51
Average age	28.73
Average number of meniscal sutures	3.1

Table 5: Site of Deployment Failure

Site of failure	Number of failures
Anchor 1	6
Anchor 2	9
Both Anchor 1 and 2	3
Neither Anchor 1 or 2 (suture failure)	2
Total	20

Table 6: Modes of Deployment Failure

Site of Failure	Mode of Failure	Number of Occurrences	Percentage of Total (%)
Anchor 1	Anchor 1 exits device without trigger	1	5
25			
	Failure to exit device	3	15
	Failure to hold in meniscus	2	10
Percentage of Anchor 1 failures			25
Anchor 2	Failure to exit device	5	25
	Failure to hold in the meniscus	4	20
Percentage of Anchor 2 failures			45
Both Anchor 1 and 2	Anchors were released together	3	25
Neither Anchor 1 or 2	Suture failure	2	10
Total		20	

Table 7: Types of Surgeries for Deployment Failure

Types of Surgeries	Number of failures	Percentage of Total (%)
ACL reconstructions Medial meniscal repair	7	37
ACL reconstructions Lateral meniscal repair	2	2
ACL reconstructions Medial and Lateral meniscal repair	3	3
PLC repair Lateral meniscal repair	1	1
Medial meniscal repair	1	1
Lateral meniscal repair	5	5

Table 8: Types of Tears for Deployment Failure

Meniscal Tear	Number of Failures (Lateral)	Number of Failures (Medial)	Average Size of Tear (mm)
Radial	0	0	5
Ramp	0	2(10%)	0
Flap/Parrot Beak	0	0	0
Root Tear	1(5%)	0	4
Bucket Handle	0	0	0
Horizontal Cleavage	0	0	0
Longitudinal Tears	1(5%)	8(42%)	12
Complex Tears	7(37%)	0	10
Degenerate Tears	0	0	0

Discussion

The results of this study confirm a small ongoing failure rate for the Fast-fix 360™ meniscal repair system, despite the device modifications undertaken by the manufacturer since its introduction. While the deployment failure rate of 4.72% in this series is lower than 11.6% reported by Bellemens et al [6] with the original Fast-fix™ design, direct comparisons are not possible. This deployment failure has secondary consequences of both increased costs and possible patient harm.

A number of failure modes were recognized. Of the twenty cases, six were due to failure of one or both anchors to hold in the meniscus (see Table 6). There are a number of possible explanations for this. One possible reason for failure may be that the potentially poor quality of the meniscus/capsule on occasion prevents the anchor from achieving an appropriate mechanical lock on the capsule. This is more likely in older patients where the quality of the meniscus may

be less than ideal. An alternative explanation may be design issues, as the new Fast-fix 360™ design has a reduced needle gauge on the delivery device and smaller suture anchors when compared to previous Fast-fix devices to reduce the secondary iatrogenic meniscal damage from device deployment. The smaller suture anchors may have less capsular mechanical fixation abilities compared to previous larger anchors.

During the study failure of one or both anchors to exit the device was the most common cause of deployment failure. This may be related to the design of the anchor mechanism. A smaller anchor may allow for more error in loading when the anchor is pushed down the needle by the deployment mechanism. The smaller anchor may not capture in the meniscus as well and tend to remain in the needle of the device if it does not engage with the meniscus, again this is supported by the high association of age over 40 and deployment failure. In 6 cases deployment failure were failures that could be attributed to the device alone. In one case the first anchor, “Anchor 1”, exited the delivery device without deployment of the trigger. In three cases both Anchor 1 and the second anchor, “Anchor 2”, deployed simultaneously, and in two cases the suture itself failed. While the Fast-fix 360™ meniscal repair system is machine loaded and the one-way sliding knot is tied mechanically, it is possible that an error may occur during packaging of the device or tying the suture.

Only six of the twenty failures were at the Anchor 1 site, with fourteen failures occurring after Anchor 1 has been deployed (see Table 5). When deployment failure of Anchor 1 occurs, iatrogenic meniscal damage risk is low as a new device can be placed into the prior needle hole if present. However, if the Anchor 1 has been placed into the meniscus and a deployment failure occurs, the risk of iatrogenic meniscal damage is much greater. Removal of the partially deployed device without iatrogenic meniscal damage can be challenging.

The modes of failure of this study are similar to that of Bellemans et al [6], analysing the failure rate of the original Fast-fix device, and each account for a similar percentage of the total failures. They reported that 17 of the 22 reported instances of failure being due to intraoperative failure, with the remainder being due to the device itself malfunctioning. This is comparable to the results of this study, where 15 of the 20 failure were intraoperative and 5 where device malfunctions.

We are not aware of any other all- inside meniscal suture device deployment failure reports. There are now a number of devices available commercially. This report may be useful to provide a benchmark for which other devices may be compared to.

There is a significant cost associated with these devices. I n Australia all meniscal suture anchor devices cost $442 per use as set by the Australian Federal Department of Health Prosthesis List. A device deployment failure occurred in 17% of cases, an extra cost of $75 per case and $8840 in this series of patients. Health care providers should be aware of the added costs associated with the use of these devices.

The main disadvantage of this study is that a direct comparison with the original Fast-fix is not possible as it is no longer manufactured. The study was performed by a single experienced surgeon in a dedicated arthroscopy theatre, and the results may not be reproduced in a general setting. Although this study encompasses a large series of cases, with a large quantity of devices being uses, the study is a disadvantaged by the lack of a control group.

Conclusion

The updated Fast-fix 360 has a 4.72% rate of deployment failure, with the commonest failure site being anchor 2 and the most common mechanism being failure of anchor to exit the device. This mode of failure is similar to reports on the original Fast-fix deployment failure.

List Of Abbreviations

Anchor 1: The first anchor of the Fast-fix device

Anchor 2: The second anchor of the Fast-fix device

Declarations

Ethics Approval and Consent to Participate:

Ethics approval was obtained prior to study set-up from the Kawana Private Hospital Ethics Committee

Consent for Publication:

Not applicable

Availability of Data and Material:

The dataset used and/or analyzed during the current study are available from the corresponding author on reasonable request

Competing interests:

The authors declare that they have no competing interests.

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Authors Contributions:

SL is the lead author and performed all surgeries and collected data. SL conceived the study and was involved in study design. AL was involved in drafting the manuscript, organising data collection design and retrieval.

CV was involved in structuring the research design and had a major hand in re-drafting the manuscript and statistics review. All authors read and approved the final manuscript.

years. Special interests include meniscal preservation techniques and ACL reconstruction surgery.

CV is a senior orthopaedic surgeon with a special interest in knee surgery in private practice for 18years. CV is an Adjunct Professor at Griffith University on the Gold Coast.

AL is an undergraduate engineering and science student at the Queensland University of Technology.

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