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Registry Data Highlight Increased Revision Rates for Endobutton/Biosure HA in ACL Reconstruction With Hamstring Tendon Autograft: A Nationwide Cohort Study From the Norwegian Knee Ligament Registry, 2004-2013

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Registry Data Highlight Increased Revision Rates for Endobutton/Biosure HA in ACL Reconstruction With Hamstring Tendon Autograft

A Nationwide Cohort Study From the Norwegian Knee Ligament Registry, 2004-2013

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Background: Compared with a patellar tendon autograft (PT), a hamstring tendon autograft (HT) has an increased risk of revision after anterior cruciate ligament reconstruction (ACLR). There are no studies analyzing whether this can be explained by inferior fixation devices used in HT reconstruction or whether the revision risk of ACLR with an HT or a PT is influenced by the graft fixation.

Purpose: To compare the risk of revision and the revision rates between the most commonly used combinations of fixation for HTs with PTs.

Study Design: Cohort study; Level of evidence, 2.

Methods: This study included all patients registered in the Norwegian Knee Ligament Registry from 2004 through 2013 who underwent primary PT or HT ACLR with no concomitant ligament injury and known graft fixation. The 2-year revision rates were calculated using the Kaplan-Meier analysis. Hazard ratios (HRs) for revision at 2 years were calculated using multivariate Cox regression models.

Results: A total of 14,034 patients with primary ACLR were identified: 3806 patients with PTs and 10,228 patients with HTs; the mean follow-up time was 4.5 years. In the HT group, 5 different combinations of fixation in the femur/tibia were used in more than 500 patients: Endobutton/RCI screw (n = 2339), EZLoc/WasherLoc (n = 1352), Endobutton/Biosure HA (n = 1209), Endobutton/Intrafix (n = 687), and TransFix II/metal interference screw (MIS) (n = 620). The crude 2-year revision rate for patients with PTs was 0.7% (95% CI, 0.4%-1.0%), and for patients with HTs, it ranged between the groups from 1.5% (95% CI, 0.5%-2.4%) for TransFix II/MIS to 5.5% (95% CI, 4.0%-7.0%) for Endobutton/Biosure HA. When adjusted for detected confounding factors and compared with patients with PTs, the HR for revision at 2 years was increased for all HT combinations used in more than 500 patients, and the combinations Endobutton/Biosure HA and Endobutton/Intrafix had the highest HRs of 7.3 (95% CI, 4.4-12.1) and 5.5 (95% CI, 3.1-9.9), respectively.

Conclusion: The choice of fixation after ACLR with an HT has a significant effect on a patient's risk of revision. In this study population, none of the examined combinations of HT fixation had a revision rate as low as that for a PT.

Keywords: ACL; reconstruction; revision; fixation; Endobutton

The most frequently used grafts in anterior cruciate ligament (ACL) reconstruction (ACLR) are a hamstring tendon autograft (HT) and a patellar tendon autograft (PT).[18] Biomechanical properties of an HT have been favorable compared with that of a PT[19] at the time of reconstruction, but concerns regarding possible inferior fixation techniques for HTs[5,21,45] have been raised. Recent studies have identified an increased risk of revision for HTs compared with PTs.[16,33,39] The revision difference between the 2 grafts was particularly large during the first postoperative year[41] when the fixation has been proposed to be the weakest link of the graft fixation complex.[5,30]

Multiple fixation devices are available, and most clinical trials comparing different fixation devices have not found

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major differences between the devices.[¶] The results of in vitro biomechanical studies[1,5,6,21,28,29] have demonstrated that most graft fixation devices investigated had sufficient fixation strength to withstand the estimated forces calculated in the ACL during various normal-day activities.[23] However, in vitro biomechanical studies with animal tissues have limitations,[38] and graft incorporation in vivo is a complex biological event. To our knowledge, there are no studies comparing revision rates for femoral or tibial fixation after ACLR.

The primary goal of this study was to investigate the risk of revision for the most common combinations of fixation for HTs in Norway and to investigate if poor fixation devices could explain the difference in the risk of revision found for HTs compared with PTs within the Norwegian Knee Ligament Registry (NKLR).

METHODS

The NKLR was started in June 2004 and is owned by the Norwegian Orthopaedic Association (NOA), with a steering committee appointed jointly by the NOA and the Oslo Sports Trauma Research Center. It is run by the Norwegian Arthroplasty Register (NAR) with funding from the Norwegian government.[17]

Registry data are collected using registration forms completed by the surgeon immediately after surgery. All surgeries on cruciate ligaments in Norway and all later knee surgeries performed on these knees are to be reported to the registry. In case of revision ACLR or if another subsequent surgery is performed, they are linked to the index operation by the patient's unique personal identification number. Reporting is voluntary, and the registry received forms from 35 public hospitals and 9 private hospitals in 2008.[48] The patients included in the registry must have signed an informed consent form before surgery. The NKLR includes endpoint revision or total knee replacement and follow-ups at 2.5 and 10 years with the subjective Knee injury and Osteoarthritis Outcome Score (KOOS).[43] The completion rate of registration to the NKLR for ACLR and revision ACLR during the years 2008 and 2009 was found to be 86% in a study comparing the data in the NKLR to those in the Norwegian Patient Register and the electronic patient charts for public and private hospitals.[48]

The surgeon's form contains detailed preoperative and intraoperative data. To report the fixation device, it is recommended that the surgeon report the catalog number of each device by using the unique barcode stickers delivered

[¶]References 9-11, 14, 15, 20, 31, 34-36, 44.

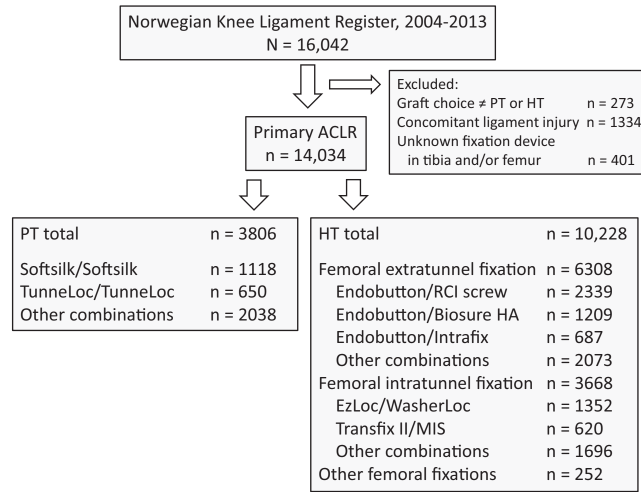

Figure 1. Flow diagram illustrating patients with fixations with a hamstring tendon autograft (HT) and a patellar tendon autograft (PT). MIS, metal interference screw.

by the manufacturers. It is possible to register multiple femoral and tibial fixations. If the registration form is incomplete, a copy is returned to the surgeon for completion.[17]

A total of 16,042 patients who underwent primary ACLR were reported to the NKLR as of December 31, 2013 (Figure 1). The following patients were excluded: patients with grafts other than HTs or PTs (n = 273), those with reported concomitant ligament injuries (n = 1334), and those with an unknown fixation device in the tibia and/or femur (n = 401). Patients with infrequently used fixation devices were grouped according to material (metal, biodegradable, or composite nondegradable) and design (interference screw, cortical button, or staple) of the fixation device. A total overview of the fixation devices used for HTs (n = 11,166) and PTs (n = 4603) in the NKLR from 2004 to 2013 is presented in Table 1.

Consequently, 14,034 patients were included: 10,228 patients with combinations of fixation with HTs and 3806 patients with PTs. In the HT group, there were 5 combinations of fixation in the femur/tibia used in more than 500 patients: Endobutton (Smith & Nephew)/RCI screw (Smith & Nephew) (n = 2339), EZLoc (Biomet Sports Medicine)/WasherLoc (Biomet Sports Medicine) (n = 1352), Endobutton/Biosure HA (Smith & Nephew) (n = 1209), Endobutton/Intrafix (DePuy Mitek) (n = 687), and TransFix II (Arthrex)/metal interference screw (MIS) (n = 620). In the PT group, there were 2 combinations of fixation for the femur/tibia used in more than 500 patients: Softsilk/Softsilk

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TABLE 1
Overview of All Femoral and Tibial Fixations for HTs and PTs Registered at Primary ACLR in the NKLR, 2004-2013[a]

Femoral Fixation		Tibial Fixation	
Device	n	Device	n
Hamstring Tendon Autograft			
Total[b]	11,166	Total[c]	11,166
Extratunnel fixation	6864	Metal IS	3816
Endobutton[f]	6258	RCI screw[f]	2850
ToggleLoc[g]	471	Other	966
Other	135	Biodegradable IS	2776
Intratunnel fixation	3878	Biosure HA[f]	1324
EZLoc[g]	1703	BioRCI[f]	491
TransFix II[h]	1039	Other	961
Rigidfix ST cross-pin kit[i]	595	Combination device	3810
Bone Mulch screw[j]	541	WasherLoc[g]	1831
IS	263	Intrafix[i]	1359
RCI screw[f]	194	BioIntrafix[i]	620
Other metal IS	46	Other/unknown	764
Biodegradable IS	23		
Other/unknown	161		
Patellar Tendon Autograft			
Total[d]	4603	Total[e]	4603
Metal IS	3959	Metal IS	4224
Softsilk[f]	1511	Softsilk[f]	1660
TunneLoc[g]	772	TunneLoc[g]	765
RCI screw[f]	472	RCI screw[f]	464
Other	1204	Other	1335
Other	448	Other	250
Rigidfix BTB cross-pin[i]	302	Staple	57
Endobutton CL BTB[f]	118	Biodegradable IS	193
Biodegradable IS	28	Other/unknown	129
Other/unknown	196		

[a]ACLR, anterior cruciate ligament reconstruction; HT, hamstring tendon autograft; IS, interference screw; NKLR, Norwegian Knee Ligament Registry; PT, patellar tendon autograft.

Additional fixation was registered in [b]25, [c]218, [d]13, and [e]60 patients.

Manufacturers: [f]Smith & Nephew, [g]Biomet Sports Medicine, [h]Arthrex, [i]DePuy Mitek, and [j]Arthrotek.

(Smith & Nephew) (n = 1118) and TunneLoc/TunneLoc (Biomet Sports Medicine) (n = 650). Endobutton is a loop suspensory fixation device made from a titanium button and a continuous polyester loop; EZLoc has a slotted titanium body with an extendable lever arm; TransFix II is a cross-pin fixation device made from titanium; RCI screw, Softsilk, and TunneLoc are cannulated titanium interference screws; Biosure HA is an absorbable cannulated interference screw that consists of a combination of poly-L-lactic acid (PLLA) and hydroxyapatite (HA); WasherLoc is a combination device consisting of a titanium spiked washer and a compression screw; and Intrafix is a combination screw and sheath device in which the expandable sheath is made from polypropylene and the screw is made from either semicrystalline or polyetheretherketone (PEEK) thermoplastic.

Statistical Analysis

Statistical analyses were performed using SPSS software (v 22; SPSS Inc). All tests were 2-sided with a .05 significance level. To test for group differences, we used the χ^2 test for categorical variables and the independent Student t test or Mann-Whitney U test for continuous variables. Crude revision rates at 2 years were calculated using Kaplan-Meier survival tables. Combinations of tibial and femoral fixations were analyzed using multivariate Cox regression analyses, with 2-year revision as the endpoint. The assumption of proportional hazards of the Cox regression model was evaluated using Schoenfeld residuals and was found suitable ($P > .44$). Patients were followed until death (n = 15), emigration (n = 14), or end of the study (December 31, 2013).

Confounding Factors

Patient age at the time of the primary reconstruction, sex, previous surgery in the index knee (yes, no, or missing), surgery time in minutes, meniscal resection (partial or complete resection to 1 or both menisci), chondral damage (International Cartilage Repair Society grades 3-4), and activity at primary injury (pivoting sports [soccer, handball, and basketball], nonpivoting sports, or other activities) were considered as possible confounding factors in the analysis. In univariate Cox regression models with revision at 2 years as the endpoint, age, sex, previous surgery in the index knee, activity at the primary injury, and surgery time were detected as possible confounding factors ($P < .2$) and entered into the multivariate Cox regression analysis.

RESULTS

Baseline epidemiological and patient characteristics for the HT combinations used in more than 500 patients and for all PT combinations used during the years 2004 to 2013 in Norway are presented in Table 2. There were statistically significant differences between the groups for all factors investigated, with a slightly larger variance for patients who had undergone previous surgery in the index knee, the number of hospitals that had used the fixation combinations, patients reaching 2-year follow-up, and surgery time.

The cumulative revision analysis stratified by the combination of fixations for HTs compared with PTs is presented in Figure 2. The crude 2-year revision rates for the fixation combinations were as follows: Endobutton/Biosure HA, 5.5% (95% CI, 4.0%-7.0%); Endobutton/Intrafix, 3.8% (95% CI, 2.3%-5.3%); Endobutton/RCI screw, 3.5% (95% CI, 2.7%-4.3%); EZLoc/WasherLoc, 2.2% (95% CI, 1.4%-3.0%); and TransFix II/MIS, 1.5% (95% CI, 0.5%-2.4%). The crude 2-year revision rate for all PT combinations was 0.7% (95% CI, 0.4%-1.0%), for Softsilk/Softsilk was 1.0% (95% CI, 0.4%-1.6%), and for TunneLoc/TunneLoc was 0.3% (95% CI, 0.0%-0.8%).

The results of the multivariate Cox regression analyses are presented in Table 3. Compared with all combinations of PT fixation, the hazard ratio (HR) for revision at 2 years was increased for all HT combinations, and the combinations

TABLE 2
Baseline Epidemiological and Patient Characteristics for All PT and HT Fixation Combinations Used in >500 Patients[a]

Variable[b]	PT Fixation[c] (n = 3806)	HT Fixation E/RCI (n = 2339)	EZL/WL (n = 1352)	E/BioHA (n = 1209)	E/Int (n = 687)	TF/MIS (n = 620)	*P*
Peak year of use	2005	2005	2006	2011	2012	2006	
Age at surgery, mean ± SD, y	28.6 ± 10.1	27.2 ± 10.1	27.4 ± 10.3	28.7 ± 10.6	29.2 ± 10.8	29.3 ± 10.7	**<.001**
Male patients, %	58.3	54.7	54.4	51.9	56.2	62.4	**<.001**
Previous surgery in index knee (n = 9891), %	21.8	20.4	20.0	15.3	20.3	31.0	**<.001**
Hospitals,[d] n	58 (16)	32 (11)	8 (7)	11 (6)	12 (3)	17 (6)	**<.001**
Meniscal resection,[e] %	35.6	31.3	35.6	41.8	32.8	31.9	**<.001**
Pivoting sport (n = 9935), %	58.7	55.9	60.7	63.5	46.6	55.6	**<.001**
ICRS grades 3-4 (n = 9977), %	7.2	7.8	4.9	6.5	3.9	6.8	**.001**
BMI <25 kg/m^2 (n = 4538), %	54.7	63.0	59.7	58.1	52.1	47.4	**<.001**
Patients with 2-y follow-up, %	79.0	77.9	94.7	51.0	72.8	94.7	**<.001**
Surgery time (n = 9909), mean ± SD, min	76 ± 32	69 ± 28	89 ± 26	49 ± 21	98 ± 25	79 ± 30	**<.001**

[a]Significant *P* values are in bold. BioHA, Biosure HA; BMI, body mass index; E, Endobutton; EZL, EZLock; HT, hamstring tendon autograft; ICRS, International Cartilage Repair Society; Int, Intrafix; MIS, metal interference screw; PT, patellar tendon autograft; RCI, RCI screw; TF, TransFix II; WL, WasherLoc.
[b]Sample size indicates the number of patients with registered factors in the data set if not complete.
[c]Includes all fixation combinations.
[d]Number of hospitals that used the specific combination of fixations in more than 50 patients during the study period.
[e]Partial or complete meniscal resection to 1 or both menisci.

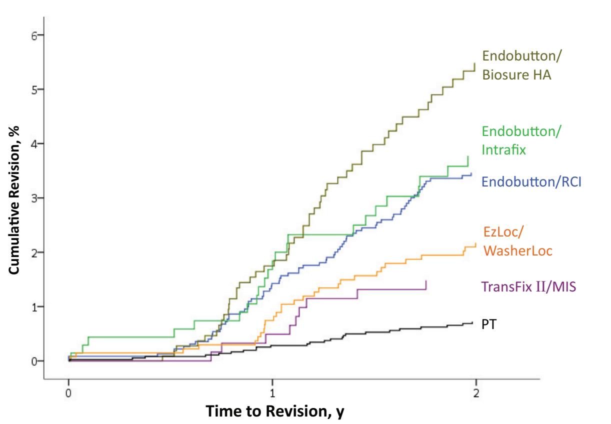

Figure 2. Overall revision analysis stratified by the combination of fixations for hamstring tendon autografts (HT) and fixation for all patellar tendon autografts (PT). MIS, metal interference screw; RCI, RCI screw.

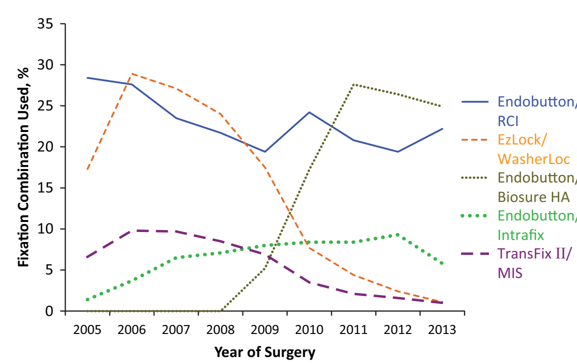

Figure 3. Time trend for the combinations of fixation for hamstring tendon autografts in the Norwegian Knee Ligament Registry. MIS, metal interference screw.

Endobutton/Biosure HA and Endobutton/Intrafix had the highest HR of 7.3 and 5.5, respectively. In a subanalysis only including patients with HTs, the HR for revision at 2 years was 1.5 (95% CI, 1.0-2.4; $P = .06$) for Endobutton/RCI screw, 2.0 (95% CI, 1.2-3.5; $P = .01$) for Endobutton/Intrafix, 2.6 (95% CI, 1.5-4.3; $P < .001$) for Endobutton/Biosure HA, and 0.8 (95% CI, 0.4-1.7; $P = .5$) for TransFix II/MIS compared with EZLoc/WasherLoc.

In a multivariate subanalysis, the relationship between the risk of revision for Endobutton/RCI screw compared with the risk with PTs remained the same in the 2 time periods of 2004-2009 (n = 1309) and 2010-2013 (n = 1030). In a multivariate subanalysis including patients with HTs with intratunnel and extratunnel femoral fixations adjusted for age, sex, activity at injury, and previous surgery in the index knee, the HR for revision at 2 years was 1.7 (95% CI, 1.3-2.2; $P < .001$) for patients with extratunnel fixation (n = 6308) compared with patients with intratunnel fixation (n = 3668). There was no statistical difference found in the HR for revision at 2 years when comparing patients with the PT fixation combination Softsilk/Softsilk with TunneLoc/TunneLoc.

The year-by-year trend in the combinations of fixation used for HTs is presented in Figure 3. Endobutton/RCI screw was used consistently during the period with 2 peaks in 2005 and 2010, with usage rates of 28% and 24%, respectively. EZLoc/WasherLoc had its peak use in 2006, with 29% of the total combinations. The combination Endobutton/

TABLE 3
Multivariate Cox Regression of Fixation Combinations for Revision and Crude Revision Rates[a]

Fixation Combination and Category	Patients/Revisions, n	2-Year Revision Rate (95% CI), %	Hazard Ratio (95% CI)	P
Patellar tendon[b]	3806/24	0.7 (0.4-1.0)	Reference	
Endobutton/RCI screw	2339/72	3.5 (2.7-4.3)	4.3 (2.7-6.9)	**<.001**
EZLoc/WasherLoc	1352/29	2.2 (1.4-3.0)	2.7 (1.6-4.8)	**<.001**
Endobutton/Biosure HA	1209/49	5.5 (4.0-7.0)	7.3 (4.4-12.1)	**<.001**
Endobutton/Intrafix	687/23	3.8 (2.3-5.3)	5.5 (3.1-9.9)	**<.001**
TransFix II/MIS	620/9	1.5 (0.5-2.4)	2.2 (1.0-4.7)	**.047**

[a]Adjusted for patient age, sex, previous surgery in the index knee, activity at the primary injury, and surgery time. Significant *P* values are in bold. MIS, metal interference screw.
[b]Includes all fixation combinations.

Biosure HA was first used in 2009, with a peak of 28% in 2011. Endobutton/Intrafix was used during the whole period, with a peak usage rate in 2012 of 9%. TransFix II/MIS was also used in the whole period, with a peak of 10% in 2006.

DISCUSSION

This is the first nationwide, registry-based cohort study analyzing the influence of the fixation device in terms of the early risk of revision after ACLR. There were 2 main findings in this study. Most importantly, there was no combination of fixation of HTs that had equally good results in terms of the 2-year revision risk as the average for PTs. Second, there were combinations of fixation for HTs with inferior results, and femoral intratunnel fixation had a lower risk of revision compared with extratunnel fixation. Based on the results found in this study and an estimated yearly average incidence of primary ACLRs in Norway of 2100, the hypothetical number of patients from a yearly cohort being revised after 2 years could potentially be decreased from 116 patients, if only HTs with the combination Endobutton/Biosure HA were used, to 32 patients, if all ACLRs were performed with the combination TransFix II/MIS. Performing all primary ACLRs with PTs could decrease the number of patients being revised to only 15. There was no difference in the risk of revision between the 2 examined PT fixations, but there might be significant differences in studies where more patients can be included.

It is proposed that the weakest link in the early postoperative phase is the graft fixation technique,[12] but there are only few comparative studies about the role of different fixation techniques for graft incorporation. It is possible that successful ACLR with an HT requires graft incorporation with solid tendon-bone healing of the graft. In our study, combinations of femoral fixation with Endobutton had a higher risk of revision at 2 years than the combinations EZLoc/WasherLoc and TransFix II/MIS, especially for the combination Endobutton/Biosure HA, which had an HR of 7.3 compared with PTs and 2.6 compared with EZLoc/WasherLoc.

We did not find any obvious reason in our data set as to why Endobutton, which has been shown to have good biomechanical properties,[2,27,28] would lead to more revisions. Ibrahim et al[25] conducted a newly published randomized clinical trial with a mean follow-up of 30 months in 70 patients comparing femoral intratunnel cross-pin fixation with bioabsorbable Rigidfix pins versus extratunnel fixation with Endobutton. On follow-up, they found no failure in stability in terms of laxity >5 mm using the KT-1000 arthrometer in the group with intratunnel fixation (n = 34) but observed 4 patients with failure in the group with extratunnel fixation (n = 32). The use of Endobutton has, in some studies, been coupled with tunnel widening.[4,13,37] Although several studies[4,7,8] reported no clinical effect of tunnel widening, Jarvela et al[26] found significantly more anterior and rotational laxity coupled with tunnel enlargement in their evidence level 1 prospective randomized study comparing tunnel enlargement in patients with double-bundle and single-bundle ACLRs. The graft-tunnel motion when using distant extratunnel fixation sites as hypothesized by Hoher et al[22] could play a role in tunnel widening. It may also affect tendon-bone healing directly[24] or indirectly by the possible negative effect of extravasation of synovial fluid between the graft and bone tunnel. Petersen and Laprell[40] examined biopsy specimens obtained at revision surgery of the femoral and tibial bone-graft interface from 6 HTs fixed with Endobutton/cramp and 8 PTs fixed with screws (n = 6) or Endobutton (n = 2) on the femoral side and screws (n = 5) or cramps (n = 3) on the tibial side. Their study suggested that there are structural differences in biological healing between the grafts, and possibly between fixation techniques, that could play a role in the strength of the graft insertion.

The combination with TransFix II and EZLoc femoral fixation had a lower risk of revision and the lowest utilization rate in the last years of the study. These devices are likely to have been fixed with a transtibial (TT) technique for femoral drill hole placement, even though Arthrex lately has developed a system for anteromedial (AM) drilling for TransFix II. Rahr-Wagner et al,[42] in a study based on data from the Danish Knee Ligament Reconstruction Register, found that the AM technique had increased in use during the study period but also had an increased risk of revision and more objective instability compared with the TT technique. However, the authors did not adjust for different combinations of fixation as a possible confounding factor. The NKLR has only included data on AM/TT drill hole placement since 2011; hence, we cannot fully adjust for this factor in our analyses. However, there was no difference in the risk of revision for the combination Endobutton/RCI screw during the early part (2004-2008) of the study when the TT technique more likely was used compared with the later part (2009-2013). We therefore suggest that the change in fixation methods that came with the AM technique could be a confounding factor in the difference found in the risk of revision between the 2 techniques. We believe that the yearly changes in the fixations used are affected by marketing from the industry and also that other factors such as surgery time for the different techniques could affect the popularity.

The tibial graft fixation site has been reported to have lower fixation strength than the femoral fixation site.[45,46] Biosure HA consists of a combination of PLLA and HA. Although PLLA screws are marked to be bioabsorbable, studies have shown that they may not be degraded several years after surgery.[32] When comparing fixation with PLLA biodegradable interference screws versus MISs in HT ACLR, previous studies have found increased tunnel widening on the femoral side[47] and an increased rate of graft failure[35] in the group with biodegradable screws. We therefore suggest that in light of the results of the current study, other alternatives than tibial fixation with biodegradable screws made of PLLA and HA should be considered.

Strengths and Weaknesses

The strength of this study is the number of patients that are included with a detailed description of the fixation devices used, making it possible to detect differences between specific devices with the low rate of revisions actually observed. Most previous studies comparing fixation devices or techniques in vivo have few patients in each group, increasing the risk of type I or II errors. With the quality and reliability of information recorded in the NAR[3] and with its multicenter design, we believe that these findings are reliable and should be applicable to the general population.

We acknowledge the presence of weaknesses in our study. First, because of the study design, we cannot exclude possible selection biases. For the combination of devices used the least in our study, there might be a risk of hospital-dependent revision rates that could influence the results; consequently, the results for these groups should be interpreted with caution.

We do not have data describing the activity level of the patient, the postoperative rehabilitation protocol followed by the patient, the graft size, or surgeon experience, which could all influence the risk of revision. We have chosen revision as the endpoint in our study, which does not include the failed procedures that are not revised. Difficulties with hardware removal could influence surgeons' willingness to revise patients with certain implants. This might influence our results to some degree, but we find it unlikely that it could explain the large differences found in our study.

CONCLUSION

We found combinations of fixation with an increased risk of revision for HTs but no combination with a similar low risk of revision for PTs. HT reconstruction with extratunnel fixation had a higher risk of revision than intratunnel fixation. In our study, femoral fixation with Endobutton, especially combined with tibial fixation and Biosure HA, had an increased risk of revision compared with PTs and also compared with other combinations of fixation for HTs.

Further studies are needed to investigate the revision risk for biodegradable interference screws. Because of the heterogeneity of the combinations of fixation used, we recommend continuous multiregistry cooperation for the early detection of inferior fixation devices.

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