Passive Knee Stability After Anterior Cruciate Ligament Reconstruction Using the Endobutton or ToggleLoc With ZipLoop as a Femoral Fixation Device

A Comparison of 1654 Patients From the Danish Knee Ligament Reconstruction Registry

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Background: Biomechanical studies show varying results regarding the elongation of adjustable fixation devices. This has led to growing concern over the stability of the ToggleLoc with ZipLoop used in anterior cruciate ligament (ACL) reconstruction (ACLR) in vivo.

Purpose/Hypothesis: The purpose of this study was to compare passive knee stability 1 year after ACLR in patients in whom the Endobutton or ToggleLoc with ZipLoop was used for femoral graft fixation. The hypothesis was that the ToggleLoc with ZipLoop would be inferior in knee stability to the Endobutton 1 year after primary ACLR.

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

Methods: Data from 3175 patients (Endobutton: n = 2807; ToggleLoc with ZipLoop: n = 368) were included from the Danish Knee Ligament Reconstruction Registry (DKRR) between June 2010 and September 2013. Data were retrieved from standardized ACL forms filled out by the operating surgeon preoperatively, during surgery, and at a clinical examination 1 year after surgery. Passive knee stability was evaluated using 1 of 2 arthrometers (Rolimeter or KT-1000 arthrometer) and the pivot-shift test. Using the same database, the number of reoperations performed up to 4 years after primary surgery was examined.

Results: Full data were available for 1654 patients (Endobutton: n = 1538; ToggleLoc with ZipLoop: n = 116). ACLR with both devices resulted in increased passive knee stability ($P < .001$). Patients who received the ToggleLoc with ZipLoop were found to have a better preoperative ($P = .005$) and postoperative ($P < .001$) pivot-shift test result. No statistically significant difference regarding the number of reoperations ($P = .086$) or the time to reoperation ($P = .295$) was found.

Conclusion: Patients who underwent fixation with the ToggleLoc with ZipLoop had improved passive knee stability 1 year after surgery, measured by anterior tibial translation and pivot-shift test results, similar to patients who underwent fixation with the Endobutton. No difference was seen in knee stability or reoperation rates between the 2 devices.

Keywords: Endobutton; ToggleLoc with ZipLoop; ACL reconstruction; cortical fixation device; soft tissue graft

Anterior cruciate ligament (ACL) reconstruction (ACLR) is one of the most common sports-related surgical procedures performed.[11] This has resulted in the development of several femoral fixation devices used to attach ACL grafts.[2,16,18] The ideal femoral fixation device should resist the daily forces to which the graft is exposed, ensuring that the graft heals in the correct position and that the knee has optimal stability.[4,18,28] Animal studies have shown that the incorporation of soft tissue autografts into bone takes between 8 and 12 weeks.[12,27] If the ACL is not sufficiently affixed in the early healing period, migration of the graft may result, causing looseness, instability, and loss of the graft and knee function.[14,18]

Passive knee stability can be measured using various methods. Anterior tibial translation can be measured with arthrometers such as the Rolimeter and KT-1000

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arthrometer.[5,10,13,22] The Rolimeter has been shown to provide equivalent anterior tibial translation measurements when compared with KT-1000 arthrometer measurements.[1,10] An insufficient ACL is defined as a difference in tibial translation between a patient's knees (side-to-side difference) of ≥3 mm when using the KT-1000 arthrometer.[6,7,26] The pivot-shift test evaluates ACL rotatory and anterior tibial displacement.[17] A positive pivot-shift test result indicates an insufficient ACL.

There are many different methods of affixing an ACL graft to the femur, one of which is the cortical fixation device.[4,8,15,21,25] These devices can be used with a transtibial tunnel technique as well. The most commonly used cortical fixation device in Denmark is the Endobutton (Smith & Nephew).[8] The Endobutton is available in various fixed-loop lengths.[4] The ToggleLoc with ZipLoop (Zimmer Biomet) is a newer cortical fixation device with an adjustable suture loop length.[2]

There is growing concern over the stability of the different cortical femoral fixation devices in vivo. There has been increased focus on adjustable femoral fixation devices, such as the ToggleLoc with ZipLoop, because of possible loop elongation and resulting slackening of the ACL graft. The biomechanical properties of the Endobutton and ToggleLoc with ZipLoop have been tested in various laboratory studies, with results showing that the ToggleLoc with ZipLoop elongates significantly more than the Endobutton.[2,15,21] Similar results have been found in animal studies in which the cortical fixation devices have been affixed to the distal end of a porcine femur.[4,15,21] To our knowledge, only 1 clinical study, by Firat et al,[9] has compared ACLR with the Endobutton versus ToggleLoc with ZipLoop in humans. Firat et al[9] included 46 patients who received the Endobutton and 32 patients who received the ToggleLoc with ZipLoop. Two years after ACLR, no significant differences in knee stability were found when evaluating the 2 patient groups with the KT-1000 arthrometer and the pivot-shift test. Such conflicting results suggest that further research with larger cohorts is needed.

The aim of our study was to compare passive knee stability in patients who underwent primary ACLR with either the Endobutton or ToggleLoc with ZipLoop 1 year after surgery. Furthermore, the number of reoperations and time to reoperation up to 4 years after primary surgery were compared for each device. The hypothesis was that at 1-year follow-up, patients undergoing ACLR with the ToggleLoc with ZipLoop would have greater anterior tibial translation and more frequent pivot shifts than those undergoing ACLR with the Endobutton.

METHODS

This was a registry-based cohort study. Data from 3175 patients were included from the Danish Knee Ligament Reconstruction Registry (DKRR)[19,23,25] between June 2010 and September 2013. This study complied with the Declaration of Helsinki and was approved by the Danish Data Committee.

Study Design

Patients from all hospitals in Denmark were included in the study if they had undergone primary ACLR with the femoral fixation device Endobutton or ToggleLoc with ZipLoop. It was up to the operating surgeon which device would be inserted. The number of surgeons who operated on the included patients was not known. Patients undergoing knee surgery involving ligaments other than the ACL were excluded, as were patients who had undergone previous ACLR on the opposite control knee. Only single-bundle ACLR was included. To avoid bias involving possible differences in revision rates, only patients with hamstring tendon autografts[24] and whose procedure was performed using the anteromedial portal[25] were included. All forms of tibial fixation devices were included (Table 1), and we included both male and female patients of all age groups.

Patients were identified in the DKRR using the Danish Civil Registration System, a system based on a unique personal identification number.[20] All public and private hospitals in Denmark report to this register, and registration is compulsory by legislation.[23] Data were retrieved from standardized ACL forms filled out by the operating surgeon preoperatively, postoperatively, and at a clinical examination 1 year after surgery, which is standard in Denmark.[19] Age, sex, side of injury, knee stability, graft fixation to the tibia, simultaneous meniscal surgery, perioperative complications, and duration of surgery were noted. Knee stability in both the injured knee and opposite control knee was evaluated using 1 of 2 arthrometers: the KT-1000 arthrometer (MEDmetric Corp) or the Rolimeter (Aircast). Furthermore, the pivot-shift test was performed by the operating surgeon on the injured knee.

Passive knee stability was only compared in patients in whom both preoperative and postoperative anterior tibial translation and pivot-shift test results were available. Meniscal treatment could not be addressed in this study because of missing data. Using the same database, we also noted the number of reoperations of all included patients from June 2010 to September 2014. Follow-up time was calculated from the time of primary ACLR to the date of reoperation or the end of follow-up in September 2014.

Patients were sorted according to their side-to-side difference in anterior tibial translation: either ≥3 mm or

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Ethical approval for this study was obtained from the Danish Data Committee (ID: AHH-2014-019; I-Suite: 03119).

TABLE 1
Tibial Fixation Devices Included in the Study

	%
Endobutton (n = 1538)	
Arthrex delta screw	0.3
Arthrex PLLA screw	0.5
Atlantech Bilok screw	1.4
Atlantech metal screw	0.1
Zimmer Biomet PEEK tibial nail (TunneLoc)	0.1
Zimmer Biomet WasherLoc	0.1
DePuy Synthes Intrafix	39.8
DePuy Synthes Biointrafix	1.9
DePuy Synthes Milagro screw	3.9
DePuy Synthes titanium screw	0.1
Inion Hexalon screw	1.0
Kramper	0.3
ConMed PLLA screw (BioScrew)	0.1
Screw/washer	2.0
Smith & Nephew PEEK screw (Biosure)	40.4
Smith & Nephew RCI Calaxo	0.1
Smith & Nephew RCI metal	1.2
Smith & Nephew RCI PLLA	0.1
Smith & Nephew Softsilk metal	0.1
Karl Storz Mega Fix	1.2
Unknown	5.5
ToggleLoc with ZipLoop (n = 116)	
Atlantech Bilok screw	7.8
Zimmer Biomet PEEK tibial nail (TunneLoc)	10.3
Zimmer Biomet WasherLoc	0.9
DePuy Synthes Intrafix	25.9
DePuy Synthes Biointrafix	20.7
DePuy Synthes Milagro screw	9.5
Smith & Nephew PEEK screw (Biosure)	12.1
Smith & Nephew RCI PLLA	1.7
Unknown	11.2

<3 mm.[6,7,10,26] Pivot-shift test results were classified as either normal (grade 0) or abnormal (grade 1 [glide], 2 [clunk], and 3 [gross]).[17]

Statistical Analysis

All statistical analyses were conducted using SPSS version 22 (IBM). The associations between femoral fixation device and sex, side of injury, preoperative and postoperative anterior tibial translation of <3 mm, preoperative and postoperative pivot-shift test results, perioperative complications, and meniscal treatment were compared using the chi-square test. The McNemar test was used to compare preoperative and postoperative pivot-shift test results and anterior tibial translation. Group differences in age and days of follow-up were compared using the Mann-Whitney *U* test. Logistic regression was used to calculate the odds ratio for reoperations for the Endobutton against the ToggleLoc with ZipLoop. Data were adjusted for age and sex. The Hosmer-Lemeshow test was used to assess the goodness of fit for the logistic regression analysis. Cox regression was used to compare the time to reoperation after primary ACLR for both devices. Data were adjusted for age and sex. *P* values ≤.05 in 2-sided tests were considered statistically significant.

TABLE 2
Patient Demographics

	Endobutton (n = 1538)	ToggleLoc With ZipLoop (n = 116)	*P*
Mean age, y	26.1	25.9	.935
Male sex, n (%)	860 (55.9)	71 (61.2)	.268
Injured right knee, n (%)	768 (49.9)	61 (52.6)	.582

TABLE 3
Patients Who Improved in Anterior Tibial Translation and the Pivot-Shift Test From Preoperatively to Postoperatively[a]

	Endobutton (n = 1538)		ToggleLoc With ZipLoop (n = 116)	
	n (%)	*P*	n (%)	*P*
Anterior tibial translation	1139 (74.1)	<.001	89 (76.7)	<.001
Pivot-shift test result	918 (59.7)	<.001	76 (65.5)	<.001

[a]Anterior tibial translation: ≥3 mm to <3 mm. Pivot shift: abnormal to normal.

RESULTS

A total of 3175 patients were included: 2807 with the Endobutton and 368 with the ToggleLoc with ZipLoop. Full preoperative and postoperative data were recorded for 1538 patients (54.8%) with the Endobutton and 116 patients (31.5%) with the ToggleLoc with ZipLoop. Patient demographics are shown in Table 2. The patients with the Endobutton attended 1-year follow-up at a mean 382 days postoperatively and patients with the ToggleLoc with ZipLoop at a mean 381 days postoperatively.

ACLR with both the Endobutton and ToggleLoc with ZipLoop femoral fixation devices resulted in increased passive knee stability, with less anterior tibial translation ($P < .001$) and improved pivot-shift test findings ($P < .001$) (Table 3). There was no significant difference between the groups in the number of patients with anterior tibial translation of <3 mm preoperatively and postoperatively (Table 4). The mean postoperative anterior tibial translation was 1.25 mm in the Endobutton group and 0.83 mm in the ToggleLoc with ZipLoop group. As seen in Table 4, some patients had an anterior tibial translation of <3 mm preoperatively and still underwent ACLR. The reasons for this are not known. A significant difference in preoperative pivot-shift test results was found between the Endobutton and ToggleLoc with ZipLoop groups ($P = .005$) (Table 5). Significant between-group differences were also found postoperatively ($P < .001$) (Table 5).

TABLE 4
Patients With Anterior Tibial Translation of <3 mm Preoperatively and Postoperatively

	Endobutton (n = 1538), n (%)	ToggleLoc With ZipLoop (n = 116), n (%)	*P*
Preoperative	103 (6.7)	12 (10.3)	.136
Postoperative	1224 (79.6)	100 (86.2)	.085

TABLE 5
Patients With a Normal Pivot-Shift Test Result Preoperatively and Postoperatively

	Endobutton (n = 1538), n (%)	ToggleLoc With ZipLoop (n = 116), n (%)	*P*
Preoperative	172 (11.2)	23 (19.8)	.005
Postoperative	1079 (70.2)	99 (85.3)	<.001

The patients with the Endobutton (n = 2807) and ToggleLoc with ZipLoop (n = 368) were followed up for a mean of 929 and 743 days ($P < .001$), respectively. In the Endobutton group, 102 patients (3.6%) underwent a reoperation, as did 7 patients (1.9%) in the ToggleLoc with ZipLoop group. The mean time to reoperation was 560 days (95% CI, 504.6-614.7) for the Endobutton group and 562 days (95% CI, 349.6-773.8) for the ToggleLoc with ZipLoop group. No statistically significant difference in the number of reoperations was found ($P = .086$). The odds ratio for reoperations was lower for the ToggleLoc with ZipLoop group (0.521 [95% CI, 0.240-1.132]) compared with the Endobutton group; however, the difference was not statistically significant ($P = .100$). The Hosmer-Lemeshow test showed adequate fit ($P = .794$). A calculation of the hazard ratio showed a similar trend (0.664 [95% CI, 0.308-1.431]), and again, it was not statistically significant ($P = .295$). There were also no statistically significant differences in perioperative complications between the groups ($P = .856$).

DISCUSSION

This is the first nationwide registry-based cohort study comparing passive anterior knee stability 1 year after primary ACLR in patients with the femoral fixation devices Endobutton or ToggleLoc with ZipLoop. Both fixation devices resulted in improvement in passive knee stability (side-to-side difference and pivot-shift test) 1 year after surgery, but differences between the 2 devices were also identified. Patients with the ToggleLoc with ZipLoop had significantly better preoperative and postoperative pivot-shift test results compared with patients with the Endobutton. This finding could, however, be examiner dependent, especially if only a minority of surgeons were using the ToggleLoc with ZipLoop. The number of surgeons in each group was not known. Similar results were found in a small study by Firat et al,[9] who compared the passive knee stability of patients with the Endobutton (n = 46) with those with the ToggleLoc with ZipLoop (n = 32) 2 years after ACLR. Firat et al[9] found no statistically significant difference between the Endobutton and ToggleLoc with ZipLoop when evaluating postoperative passive knee stability with the KT-1000 arthrometer and the pivot-shift test.

Despite the statistically significant difference in pivot-shift test results found in our study, both groups significantly improved in the pivot-shift test after surgery. The use of either device is not expected to produce any differences of clinical importance and, therefore, will not affect the favorability of one device over the other.

The rate of reoperation of the reconstructed ACL was low for both devices. No statistically significant difference between the devices was found regarding the risk of reoperations over time. Reoperations occurred in most cases in the first 2 years after primary surgery. There was a significant difference in days of follow-up between the groups. The mean follow-up time in both groups, however, exceeded 2 years, ensuring that the majority of reoperations were identified. This finding further indicates the similar performance of the 2 devices. It should, however, be noted that in both groups, some patients had postoperative anterior tibial translation of ≥3 mm and/or a positive pivot-shift test result.

The fixed-loop length of the Endobutton can offer some practical challenges when placing the device into position. The femoral tunnel and the loop length need to match. Misjudgment in the femoral tunnel length versus loop length may result in the Endobutton being too long or too short, causing problems either with the position of the device or insufficient graft-bone contact.[3]

The ToggleLoc with ZipLoop has an adjustable loop, and therefore, the loop length does not need to be considered with the same degree of accuracy as when using fixed-loop devices. Because the loop is adjustable, there is a possible risk of lengthening.[4,15] The final adjustment of the ToggleLoc with ZipLoop device may contribute to optimal placement of the graft in the tunnel. Another advantage of adjustable loop devices is the ability to tension the femoral side after tibial fixation.

In their biomechanical study, Barrow et al[2] found that the ToggleLoc with ZipLoop elongated by 3 mm after a mean 2576 ± 73 cycles of testing compared with the Endobutton, which elongated by a mean 1.34 ± 0.03 mm after 4500 cycles. Kamelger et al[15] found that the mean plastic displacement during device testing ranged from 0.15 ± 0.01 mm after 1000 cycles for the Endobutton CL 20-mm loop to 0.66 ± 0.12 mm for the ToggleLoc with ZipLoop 20-mm loop. Petre et al[21] had similar results, showing that the displacement after 1000 cycles during isolated device testing was 0.11 mm (SD, 0.03) for the Endobutton and 0.82 mm (SD, 0.18) for the ToggleLoc with ZipLoop.

Elongation of the ToggleLoc with ZipLoop seen in biomechanical studies did not translate into postoperative clinical knee instability in our patients. There was no significant difference in the number of patients with a postoperative anterior tibial translation of <3 mm between the Endobutton group (mean, 1.25 mm) and the ToggleLoc with

ZipLoop group (mean, 0.83 mm). The healing process may account for this discrepancy between the biomechanical and in vivo studies. The graft is not fully incorporated in the bone until 8 to 12 weeks after surgery.[12,27] The healing process, however, begins immediately after surgery, when incorporation of the graft into the bone may give added support. Postoperative rest and the use of crutches in the days after surgery are thought to reduce forces that the ACL graft would otherwise be exposed to, thus promoting correct graft placement, a faster healing process, and ultimately, added stability to the knee. The threshold for elongation of the ToggleLoc with ZipLoop might, therefore, not be reached because of the extra support provided by graft-bone incorporation and the use of crutches. This added support is not present in biomechanical studies, in which the ToggleLoc with ZipLoop device must stand alone in holding the graft in place against various loads.[4]

Another problematic factor in biomechanical studies is the difference in the load angle. All loads added to the femoral fixation device are pulled in a straight line through the femoral tunnel. This results in maximal load transfer to the femoral fixation device. The loading force would rarely be that linear in vivo.[15,21] Therefore, the loads that the femoral fixation device has to resist may be lower in vivo. The loading threshold for elongation might not be exceeded as easily in vivo, and this could explain why the ToggleLoc with ZipLoop does not elongate to the same extent as seen in biomechanical studies.

Limitations

This study has several strengths and limitations, as it is based on data from a national clinical registry. The DKRR is a large national database. All public and private hospitals in Denmark report to this register, and registration is compulsory by legislation. This is a clear strength for the quality of the data. Furthermore, the DKRR provides an unselected study population because of unrestricted and free access to health care in Denmark. A national clinical registry has, however, several limitations. Full preoperative and postoperative data were recorded for only 54.8% of patients with the Endobutton and 31.5% of patients with the ToggleLoc with ZipLoop. A substantial amount of data was missing, as some patients did not undergo the 1-year clinical examination. It is unlikely that the lack of these data is associated with knee instability and revision because data collection is prospective and the registration of primary ACLR is independent of the registration of later revision. The revision rate was low in both groups.

The use of several different tibial fixation devices, as seen in Table 1, is a confounder and can potentially affect passive knee stability and the revision rate. To increase the number of patients included in the study, all tibial fixation devices were accepted. There are other possible confounders, such as differences in physical activity levels, quality of rehabilitation, and patient compliance, that have not been taken into account.[25] Patient-reported outcome data and return-to-sport data were missing in this study. Meniscal treatment could not be addressed because of missing data. The clinical examination was, at most hospitals, carried out by the same surgeon who performed the surgical procedure, which could have introduced bias in relation to the interpretation of surgery outcomes. This danger is, however, present for both fixation devices. The number of surgeons in each group was not known. If fewer surgeons used the ToggleLoc with ZipLoop, the risk of interpretation bias would increase.

CONCLUSION

Despite the findings of biomechanical studies, it appears that the ToggleLoc with ZipLoop provided knee stability that was at least as good as the Endobutton. Patients in both the Endobutton and ToggleLoc with ZipLoop groups had improved passive knee stability 1 year after ACLR, as assessed by anterior tibial translation and the pivot-shift test. The elongation seen in biomechanical studies did not translate into postoperative clinical knee instability in our patients. No statistically significant difference between the 2 devices could be documented regarding the number of reoperations and the time to reoperation. Further clinical studies are needed to evaluate the performance of adjustable and fixed-loop devices.

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