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Evaluation of Adjustable Loop Suspensory Anterior Cruciate Ligament Fixation Devices

Abstract: Along with increasing enthusiasm for sports comes an increase of sport related injuries. One of the most common injuries in the human knee is the tear of the anterior cruciate ligament (ACL). The selection of a graft fixation device is an important factor that determines the outcome of an anterior cruciate ligament reconstruction. Before the healing process is completed, the graft is dependent on tibial and femoral fixation devices to maintain normal ACL graft tension. Among various devices, the use of an adjustable loop suspensory fixation device (ALD) in soft-tissue graft reconstruction attracts current interest. An advantage of the ALD is the ability to draw the graft to the depth of the bone tunnel to achieve adequate graft tension while minimizing the empty space in the tunnel. In this study a comprehensive controlled laboratory investigation is performed to examine the biomechanical properties of commonly used cortical fixation devices, with the aim of implementing a standard testing procedure for adjustable loop devices. The procedure consists of three test series, a loop shortening test and two different stability test series (single device and tendon device test). Those test series are used to compare the performance of a new ALD from Arthrex (Naples, USA) with five competitor devices already on the market. In order to obtain representative results eight samples of each device are tested. In comparison to the previously performed studies, a complete unloading is applied in the stability tests, which allows for a detailed examination of the ALDs locking mechanisms in dynamically loaded test situations. Furthermore, the performed loop shortening tests reveal important aspects, such as the shortening accuracy and settling effects of the loops, that are not found in previous studies. Therefore, the used test protocol can be recommended for further testing.

Keywords: anterior cruciate ligament reconstruction, adjustable loop device, fixed loop device, biomechanical testing

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1 Introduction

The tear of the ACL is one of the most common knee injuries [1–4]. Athletes practicing sports like skiing, soccer, tennis, squash, and volleyball are likely to hurt their ACL due to a prompt change of direction, fast stop and go movements, landing incorrectly from a jump or even due to a direct contact or collision [1, 5, 6]. Since the tear of the ACL generally occurs as a sport injury, mainly young people are affected [2]. There are many ways to treat an ACL injury, including the operative reconstruction, which is considered as the gold standard especially for young active patients who wish to return to active sports as fast as possible. During the reconstruction, the remaining parts of the ligament are removed and an allograft or autograft from either the hamstring or patella tendon is implanted in order to substitute the ACL. [1, 7] The implanted graft can be attached to the femur and tibia with for example a metal or bio-interference screw, a dissolving bioscrew, a biodegradable or metal pin, a fixed loop device or an adjustable loop device [4]. This study evaluates the performance of a new ALD compared to five competitor devices.

2 Materials and Methods

In order to compare the ALDs three test series were performed, a loop shortening test and two different stability test series. Six ALDs were used in this study with a sample size of $n=8$. Additionally, two groups of fixed loop devices were included as reference groups. The devices shown in Figure 1 were used.

Figure 1: The eight different groups of cortical fixation devices are presented. (A) RetroButton (Arthrex, USA), (B) EndoButton (Smith and Nephew, Great Britain), (C) GraftMax (ConMed Linvatec Inc., USA), (D) UltraButton (Smith and Nephew, London, Great Britain), (E) ProCinch (Stryker, USA), (F) ToggleLoc (Biomet, USA), (G) RigidLoop (Mitek Sports Medicine, DePuy Synthes, Switzerland), (H) new ALD (Arthrex, USA).

For all three test series, a biomechanical dynamic testing machine with a dynamic load cell was used. After completing the test series, the data sets were evaluated using the following three programs: GOM Correlate Professional (GOM GMBH, Braunschweig, Deutschland, 2017), Microsoft Excel (Microsoft Corporation, Redmond, USA, 2016) and Matlab (Mathworks Inc., Natick, USA, 2017).

2.1 ALD Loop Shortening Test

The loop shortening tests were performed to evaluate and compare the loop shortening behaviour of the ALDs. Two different aspects were included, the accuracy of the shortening mechanism and the settling effects of the loops. Furthermore, an optical measurement system, which can detect 3D movements, was connected to the biomechanical testing machine. The test setup included a slotted disc, where the buttons were placed, and the loops could be threaded through. The shortening strand was trapped in the suture clamp of the testing machine and the hook was mounted into the loop. Five marker-dots were placed on the hook to detect its 3D position with the optical measurement system. Every sample was tested at six load-levels, regarding the load applied to the loop via the hook. The tests were performed according to the following protocol shown in figure 2. To quantify the settling effects of the ALDs, a total bounce back (*tbb*) was defined as the length of the setting effects of the ALDs. It is calculated as the difference of the vertical position of the hook between image G4 and image G2.

Figure 2: Schematic representation of the loop shortening test process.

2.2 Stability Test Series

To evaluate the irreversible elongation of the adjustable loop devices under cyclic loading, stability tests were performed in two different test series. First, a single device test was

executed, to test the isolated mechanical properties of the ALDs. In continuation, the ALDs were tested in combination with a tendon to investigate their behaviour in an environment closer to that of the clinical application. Monaco et al. [8] reported that repetitive loading and complete unloading situations are the most adequate conditions to evaluate the stability of ALDs. Thus, for each sample 3000 cycles of loading and complete unloading with increasing load levels between 50 N and 300 N were performed. The maximum load level of 300 N was chosen according to previously performed studies [9, 10]. Barrow et al. [9] and Ahmad et al. [11] defined an absolute displacement of 3 mm as clinical failure, this value was considered as failure criterion for the tested samples. For the single device test (see figure 3A) the ALDs and FLDs were fixed in the setup between two metallic components to apply loads on the device. The cortical button and suture loop were fixed onto a slotted disc (indicated in brown in figure 3A and B) attached to the test machine actuator. A pin (shown in green in figure 3A) on the baseplate of the machine secured the suture loop. The force was applied through an up and down movement of the test machine actuator (figure 3A and B, red). This test setup represents worst case conditions, since the forces are transmitted with very little friction loss at the metallic pin. To simulate an intra-articular environment the tests were performed in an aqueous environment. For the device tendon test the pin used to secure the loop was substituted by a bovine tendon (see figure 3B) to represent the elastic behaviour occurring in the clinical application.

Figure 3: Schematic drawing of the single device test set up (A) and the device tendon test set up (B).

3 Results

3.1 ALD Loop Shortening Test

Figure 4 shows the final loop length at six different load levels for the tested adjustable loop devices after nominal shortening of 10 mm. The final loop length values were recorded by the optical camera system after shortening the loop, but before unloading the shortening strand of the devices. The results of *RigidLoop*, *UltraButton*, and the *new ALD* show a similar shortening behaviour with a shortening close to the expected length of 10 mm. The *ProCinch* and *ToggleLoc* devices already have higher loop length deviations at smaller load levels with a steady increase until reaching the final load. The group of *GraftMax* shows a wide intragroup variation, which is represented by the high standard deviation, especially at the first load level.

Figure 4: Loop shortening (mm) as a function of the load levels (N) for the different tested ALD groups. The shown values are the average of eight measurements and the error bars represent the standard deviation between those measurements. The red line indicates the expected position after the shortening.

3.2 Stability Test

The displacement of the loop is presented as a function of the number of tested cycles for each of the eight tested groups (see figure 5). The grey lines display the results of the single device test, while the black lines show the results of the device-tendon test series. For a better comparability the clinical failure of 3 mm is marked with a red line. The *ProCinch* group reaches clinical failure within the first 1000 cycles while the *ToggleLoc* devices reach the limit within the first 1500 cycles. *UltraButton* and *GraftMax* also reach clinical failure before the ending of the tests. *Rigidloop* and the *new ALD* show a similar behaviour to the two groups of FLDs, *EndoButton* and *RetroButton*, and do not reach clinical failure before the

defined test end. Furthermore, the *new ALD*, *UltraButton* and *ProCinch* show improved results in the device-tendon test series compared to the single device tests, while *RigidLoop* shows impaired results in this series. The FLDs also show worse results in the device-tendon test series than in the single device tests. The results for *GraftMax* are slightly better in the device-tendon series, while those of *ToggleLoc* show nearly no difference between the two series.

Figure 5: Absolute displacement as a function of the cycles of loading and unloading for each tested group.

4 Discussion

RigidLoop, the *new ALD*, and the *UltraButton* devices have a similar satisfying shortening behaviour, while the groups of *ProCinch*, *ToggleLoc* and *GraftMax* show a significantly worse behaviour. *ToggleLoc* is the only device that uses an antegrade shortening mechanism, where all sutures run through the same hole in the button, which may be the reason for the worse shortening behaviour. The poor shortening

behaviour of *ProCinch* is induced by the rotational movement of the suture, which occurs at the beginning of the shortening process. When the shortening strand of *GraftMax* is pulled, an initial lift of the button occurs and the actual loop shortening starts delayed. The total bounce back of the *GraftMax* group is significantly higher than for the other tested groups, which results from the initial tilting of the button, since the tilting of the button is reversed when the shortening strand is unloaded. From the six tested ALD groups, only the *new ALD* and *RigidLoop* do not reach clinical failure. Glasbrenner et al. [10] evaluated whether ALDs with a locking mechanism based on a chinese finger trap (CFT) resist cyclic loading and complete unloading. They determined significantly worse results for ALDs with a locking mechanism based on a CFT than for ALDs with a button lock. Since *ProCinch*, *UltraButton* and *ToggleLoc* are the only tested devices, with a locking mechanism based only on a CFT, the same observation is made here. Ahmad et al. [11] reported that the devices *ProCinch* and *Ultrabutton* do not reach clinical failure within their 2000 cycle protocol. However, their protocol does not include complete unloading, which could be the reason for the different results as a remaining minimum of load may improve the stability of an ALD.

5 Conclusion

The biomechanical comparison of the adjustable loop devices reveals that *RigidLoop* and the *new ALD* are the only devices that do not reach clinical failure. These devices even show a behaviour similar to the fixed loop devices *EndoButton* and *RetroButton*, which are tested as reference groups. In conclusion, the test results show that a combination of two locking mechanisms leads to an improved stability of the loop. The implemented testing protocols for all test series allow for a critical evaluation of different available ALDs on the market, with a good comparability between the tested groups. Therefore, the used test protocol can be recommended for further testing. As the implementation of the tendon reveals a significantly different outcome of the results in the stability tests, it should be considered to add a tendon to the tensioning test series, in order to perform this series in an environment closer to the clinical application.

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References

- [1] A. M. Kiapour and M. M. Murray, "Basic science of anterior cruciate ligament injury and repair," (eng), *Bone & joint research*, vol. 3, no. 2, pp. 20–31, 2014.
- [2] Harald Wildhalm, "Kreuzbandriss," *ÖAZ*, no. 18, 2017.
- [3] T. E. Hewett, S. L. Di Stasi, and G. D. Myer, "Current concepts for injury prevention in athletes after anterior cruciate ligament reconstruction," (eng), *The American journal of sports medicine*, vol. 41, no. 1, pp. 216–224, 2013.
- [4] H. S. Kim, J. K. Seon, and A. R. Jo, "Current trends in anterior cruciate ligament reconstruction," (eng), *Knee surgery & related research*, vol. 25, no. 4, pp. 165–173, 2013.
- [5] M. Schünke, E. Schulte, U. Schumacher, M. Voll, and K. Wesker, Eds., *Prometheus*, 2005.
- [6] W. Petersen and T. Zantop, *Das vordere Kreuzband: Grundlagen und aktuelle Praxis der operativen Therapie; mit 29 Tabellen*: Deutscher Ärzteverlag, 2009.
- [7] P. Mahapatra, S. Horriat, and B. S. Anand, "Anterior cruciate ligament repair - past, present and future," (eng), *Journal of experimental orthopaedics*, vol. 5, no. 1, p. 20, 2018.
- [8] E. Monaco et al., "Intraoperative Workflow for All-Inside Anterior Cruciate Ligament Reconstruction: An In Vitro Biomechanical Evaluation of Preconditioning and Knot Tying," (eng), *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, vol. 34, no. 2, pp. 538–545, 2018.
- [9] A. E. Barrow, M. Pilia, T. Guda, W. R. Kadmas, and T. C. Burns, "Femoral suspension devices for anterior cruciate ligament reconstruction: do adjustable loops lengthen?," (eng), *The American journal of sports medicine*, vol. 42, no. 2, pp. 343–349, 2014.
- [10] J. Glasbrenner et al., "Adjustable buttons for ACL graft cortical fixation partially fail with cyclic loading and unloading," (eng), *Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA*, 2018.
- [11] S. S. Ahmad et al., "Adjustable loop ACL suspension devices demonstrate less reliability in terms of reproducibility and irreversible displacement," (eng), *Knee surgery & related research*, vol. 26, no. 5, pp. 1392–1398, 2018.