International Orthopaedics (SICOT) (2014) 38:2499–2503
DOI 10.1007/s00264-014-2483-y

ORIGINAL PAPER

The biomechanics of biodegradable versus titanium interference screw fixation for anterior cruciate ligament augmentation and reconstruction

Max Ettinger · Diana Schumacher · Tilman Calliess · Antonios Dratzidis · Marco Ezechieli · Christof Hurschler · Christoph Becher

Received: 6 July 2014 / Accepted: 25 July 2014 / Published online: 15 August 2014

Abstract
Purpose The ligament augmentation and reconstruction system (LARS) is one of the options available for anterior cruciate ligament (ACL) reconstruction. To date, however, there are no published data regarding the biomechanical properties of LARS fixation for ACL reconstruction. The aim of this study was to investigate the biomechanical properties of various LARS interference-screw fixations.
Methods A total of 100 LARS ligaments were fixed in porcine femurs with five different interference screws (four biodegradable screws and one titanium interference screw) introduced from inside-out or extra-articularly outside-in. Each group consisted of ten specimens. The constructs were cyclically stretched and subsequently loaded until failure. We evaluated the maximum load before failure, elongation during cyclic loading, stiffness, and failure mode.
Results Elongation during cyclical loading for all devices tested was significantly larger between the first and 20th cycles than between the 20th and 500th cycles ($p<0.05$). Maximum failure load was not significantly lower for the biodegradable screws than for the titanium screws ($p>0.05$). All specimens failed because of ligament pull-out from the bony tunnel.
Conclusions Our findings suggest that biomechanical secure fixation of the LARS for ACL reconstruction can be achieved using either biodegradable or titanium interference screws. The stability of fixation is independent of the approach, type of investigation, and type of fixation (extra-articular outside-in or intra-articular inside-out).

Keywords LARS · ACL reconstruction · ACL biomechanics · Interference screw

M. Ettinger (✉) · D. Schumacher · T. Calliess · A. Dratzidis · M. Ezechieli · C. Becher
Department of Orthopaedic Surgery, Hannover Medical School, 1-7 Anna-von-Borries Street, Hannover 30625, Germany
e-mail: max.ettinger@ddh-gruppe.de

C. Hurschler
Department of Biomechanics and Biomaterials, Hannover Medical School, Hanover, Germany

Introduction

The ligament augmentation and reconstruction system (LARS; Surgical Implants and Devices, Arc-sur-Tille, France), which consists of polyethylene terephthalate (PET), has been available for anterior cruciate ligament (ACL) reconstruction for two decades [19]. This synthetic material was popular for ACL reconstruction during the early 1990s. After problems associated with the material were reported, however, interest and application waned significantly [6, 19]. Currently, interest in PET devices has arisen once again, particularly in Australia and Asia [7, 14], as problems such as synovitis and tendon ruptures are no longer being reported. Applications of new material have been proposed. To date, however, clinical and biomechanical data for this device are sparse. To our knowledge, in the only prospective randomized trial comparing LARS to bone–patellar tendon–bone (BPTB) ACL reconstruction, no differences were found in clinical outcomes with regard to complications and failure rates [13]. The proponents of this device claim faster rehabilitation, lack of donor-site morbidity, and reduced operating time. The LARS consists of intra-articular and extra-articular sections, the former consisting of single free fibres. Potential advantages include resistance to fatigue and a porous surface, which may facilitate osseous integration [14]. In contrast to the intra-articular portion of the device, the extra-articular portion is composed of knitted fibers combined with longitudinal fibers, which are designed to provide strength and resistance to elongation [14].

This design is intended to surmount the issues, which were believed to cause synovitis and tendon rupture.

The LARS device may serve as a scaffold to augment a ruptured ACL temporarily and ensure secondary healing. Thus, preservation and suturing of the ACL stump is required [14]. In the literature, the device was always fixed from outside-in. For osseous fixation, it has been recommended to fix the device with specially-designed titanium interference screws. The thread of the screws has blunt edges so it compresses but does not cut the material while locking the ligament securely. At the femoral insertion site, it is recommended that the screw be inserted extra-articularly to preserve the ACL stump. Despite several potential advantages, this approach is compromised by artifacts that arise during postoperative magnetic resonance imaging and the need for implant removal in the case of ACL revision surgery [15]. Conversely, inside-out fixation appears preferable because possible bungee and/or windshield-wiper effects are minimized by fixation closer to the joint line [8].

To our knowledge, there are no data available regarding the biomechanical properties of the LARS device in combination with titanium screws or with modern biodegradable interference screws. The purpose of this study was to characterize the biomechanical properties of various interference screw fixations wherein the LARS device is fixed using both an inside-out and a conventional approach. We hypothesized that commonly used biodegradable interference screws do not result in inferior biomechanical properties with respect to maximum failure load, elongation during cyclic loading, stiffness, or failure mode when compared with titanium screws.

Material and methods

As a model of the implantation site, the femurs of 100 German Landrace pigs were used. The pigs were one year old, fully grown, and weighed 180–220 kg. The femoral neck was transected, and the femoral shaft was cemented into an aluminum holder using cold-curing methylmethacrylate resin (Technovit 4071; Heraeus Kulzer GmbH, Wehrheim, Germany). All bony tunnels were drilled with a 7-mm reamer. As all 100 LARS ligaments (AC 120) had a diameter of 7.5 mm, 8-mm screws were used for fixation according to the manufacturer's user's guide (www.larsligaments.com).

Extra-articular outside-in and intra-articular inside-out interference screw fixations (Fig. 1a, b) were evaluated using the following screws (Fig. 2):

1. Titanium (8×30 mm; LARS; Surgical Implants and Devices, France)
2. Milagro Bioreplaceable Interference screw (8×23 mm; DePuy Mitek, Warsaw, IN, USA)

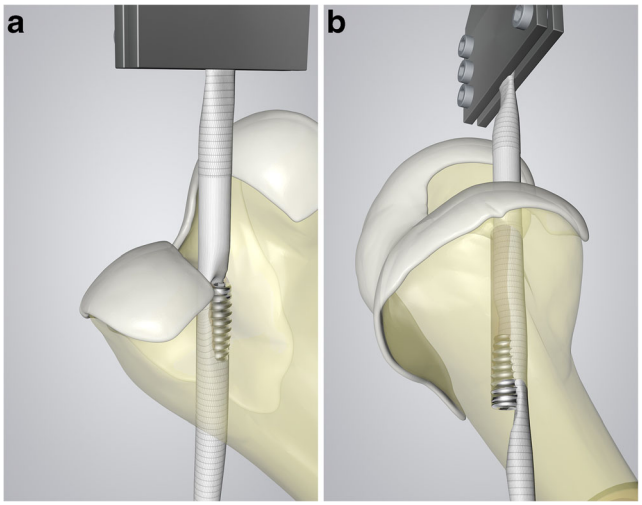

Fig. 1 Fixation techniques investigated. **a** Inside-out technique. **b** Outside-in technique

3. Bioact IF Osteotrans (8×25 mm; Richard Wolf, Knittlingen, Germany)
4. BioComposite Interference screw (8×23 mm; Arthrex, Munich, Germany)
5. Mega Fix Interference screw (8×23 mm; Karl Storz, Tuttlingen, Germany)

Mechanical testing protocol

A material testing machine (Mini Bionix 858; MTS Systems, Minneapolis, MN, USA) was used for mechanical evaluation of the constructs. Each group consisted of ten constructs. The potted femurs were rigidly fixed in a base platform at 50°, with the bone tunnel force direction angle at 0°. There was a distance of 30 mm between the graft and the clamp.

The constructs were pretensioned with 60 N for 30 seconds prior to testing. Then, 500 cycles of mechanical loading of 60–250 N were applied at a repetition rate of 1 Hz. The increase in construct length was recorded at a frequency of 20 Hz and a measurement accuracy of 0.1 mm. Length changes were reported between the minimum of the first (20th) and the maximum of the 20th (500th) cycles. After decreasing the preload from 60 to 10 N and pausing for 30 seconds, a failure test with a ramp speed of 1 mm/s was performed. The maximum failure load, stiffness, failure mode, and elongation of the constructs were analysed.

Statistical analysis

All mean values are reported with standard deviations. The groups were compared using a one-way analysis of variance (ANOVA). Normality and equal variance tests were

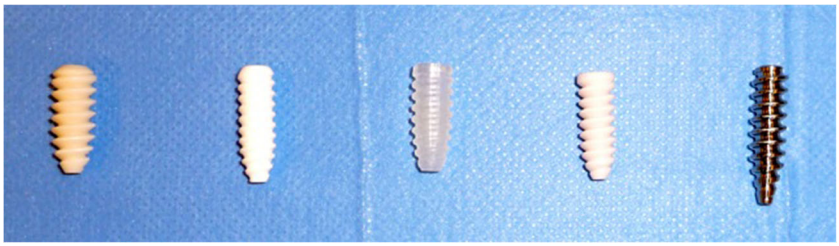

Fig. 2 Screws that were tested (*from left to right*): titanium (LARS) (8×30 mm). Milagro Bioreplaceable Interference screw (8×23 mm), Bioact IF Osteotrans (8×25 mm), BioComposite Interference screw (8×23 mm), Mega Fix Interference screw (8×23 mm)

conducted. If the normality test failed, a Kruskal–Wallis ANOVA on ranks was executed with a post-hoc Scheffe test. If normality tests were passed, an equal variance test was conducted. All operations were performed using Sigma Stat 15.0 (SPSS, Chicago, IL, USA). A significance level of $p<0.05$ was assumed.

Results

The strength of the Milagro, BioComposite, and Mega Fix screws was superior to that of the Osteotrans screw in regard to the maximum load to failure ($p<0.05$) (Table 1). The strength of the Milagro and BioComposite screws was superior to that of the titanium screws ($p<0.05$) (Table 2).

Elongation between the first and 20th loading cycles was significantly different from that between the 20th and 500th loading cycles for all groups ($p<0.05$). Elongation between the first and 20th loading cycles and between the 20th and 500th loading cycles was not significantly different between the groups (Table 1).

The stiffness also was not significantly different ($p<0.05$). The results are presented in detail in Table 2.

The mode of failure was slippage of the graft between the screw and the bone tunnel in all cases. None of the LARS devices showed any visible signs of damage after the testing.

Discussion

The most important finding of this study was that the LARS device, fixed with the various interference screws, showed biomechanical properties comparable to those seen with other hardware fixations for ACL reconstruction. The Milagro and BioComposite screws showed strength superior to even that of the titanium screw. We demonstrated that inside-out and outside-in introduction of the screws are both good options in regard to biomechanical properties.

Sufficient primary stability of the graft fixation is crucial for adequate early postoperative rehabilitation. The maximum failure loads observed in this study were superior to those for soft-tissue interference screw fixation, which were evaluated with a comparable setup [1–3, 10, 21]. Additionally, they were comparable to the maximum failure loads for other hardware fixation systems, such as the Bone Mulch screw (1,112± 295 N) or the EndoButton (1,086±185 N) [10]. We assumed that this was due to the fact that all specimens were fixed at 1 mm over size. Significantly different failure loads were observed between the devices in this study for both types of implantation. The differences may be attributable to the differences in the screw designs (geometry, core diameter, pitch/thread height) [10]. Weiler et al. [18] showed that screw design plays an important role in determining the strength of BPTB grafts, although it may not be the same for hamstring grafts [17].

The presented stiffness data are superior to those for other interference screw fixations using soft-tissue grafts [10], whereas the data are comparable to those found with the Bone

Table 1 Elongation between the first and 20th loading cycles and the 20th and 500th loading cycles. Elongation between the first and 20th loading cycle was significantly greater for all groups than that between the 20th and 500th loading cycle ($p<0.05$). There were no significant differences between the first and 20th loading cycles or between the 20th and 500th loading cycles between groups

Measure (mm)	Mitek i 1–20	Mitek e 1–20	Arthrex i 1–20	Arthrex e 1–20	Storz i 1–20	Storz e 1–20	Wolf i 1–20	Wolf e 1–20	Titanium i 1–20	Titanium e 1–20
Ø	10.62	11.11	10.47	10.83	11.05	11.00	12.76	12.01	11.29	12.65
SD	1.12	1.09	1.81	1.16	1.81	1.45	1.05	1.25	1.99	1.11
Measure (mm)	Mitek i 20–500	Mitek e 20–500	Arthrex i 20–500	Arthrex e 20–500	Storz i 20–500	Storz e 20–500	Wolf i 20–500	Wolf e 20–500	Titanium i 20–500	Titanium e 20–500
Ø	1.11	1.09	1.51	0.66	1.32	0.70	1.38	1.70	1.41	0.83
SD	0.51	0.60	0.47	0.27	0.61	0.30	0.76	0.44	0.27	0.39

Table 2 Maximum load to failure for the screws tested: Milagro, BioComposite, Mega Fix, BioComposite, titanium screws. The Milagro, BioComposite, and Mega Fix screws showed strength superior to that exhibited by the Bioact IF Osteotrans screw concerning the maximum load to failure ($p<0.05$). The Milagro and BioComposite screws showed strength superior to that of the titanium screws ($p<0.05$). The stiffness was not significantly different among the groups

Measure	Wolf (I)	Wolf (E)	Storz (I)	Storz (E)	Mitek (I)	Mitek (E)	Arthrex (I)	Arthrex (E)	Titanium (I)	Titanium (E)
Mean (N)	795.1	707.6	936.4	966.4	1,068	1,177	1,061	1.036	858.4	836.7
Std. deviation	133.6	104.6	168.4	169.3	183.5	161.9	183.6	148.7	132.6	128.8
Measure	Mitek (I)	Mitek (E)	Arthrex (I)	Arthrex (E)	Storz (I)	Storz (E)	Wolf (I)	Wolf (E)	Titanium (I)	Titanium (E)
Mean (N/mm)	141.2	143.0	141.4	145.6	143.8	141.0	133.4	138.8	141.6	141.0
Std. deviation	3.8	7.3	10.5	6.9	5.7	3.5	3.6	4.4	6.7	8.1

Mulch Screw (115±28 N/mm) and the EndoButton (79.0± 7.2 N/mm). These observations suggest that stiffness may be related to the low elasticity of the LARS device.

Without exception, the tested specimens failed because of pull-out from the LARS device. This is comparable to the findings of other studies in which soft-tissue grafts were fixed with interference screws [10, 21].

We chose a strain rate of 1 mm/s in accordance with recent similar investigations that focused on the biomechanical properties of cruciate ligament reconstruction [4, 5, 9]. The 250 N peak cyclic load in this study was lower than the estimated 350 N in vivo force during normal walking that was described by Morrison et al. [11]. We believe that this finding was not important as the focus of our study was on the initial postoperative period during which lower graft forces are expected.

The importance of preconditioning a soft-tissue graft was demonstrated previously in vitro [12] and in vivo [20]. The results of our study showed that the entire tested graft fixation construct yielded around 10 mm during the first 20 loading cycles between 50 and 250 N. In contrast, the constructs yielded only an additional 0.4–1.7 mm during the next 480 loading cycles. The initial increase in the residual displacement most likely resulted from typical creep of the graft–construct fixation. This could most likely be minimized in the clinical setting by meticulous preconditioning of the graft before the final fixation. Thus, we considered the first 20 cycles of this study as cyclical preconditioning. This reasoning underlines the importance of graft preconditioning.

Several study limitations must be addressed. First, we examined the biomechanical properties of the LARS device fixed into porcine femors. The use of porcine bone has been criticized in the literature [16] mainly because of overestimation of failure loads and graft slippage while evaluating interference screw fixation. We chose the porcine femor because of its uniform bone quality in pigs of the same age. The screws and the operative approach were thus the only meaningful factors influencing the experimental setup. Another limitation is that we focused on a single tunnel force angle of 0°. This is the so-called worst-case scenario. Consequently, we have no knowledge about the effect of flexion and extension motion or of different tunnel force orientations. Finally, this controlled laboratory study—as is typical for experimental studies—reflects the mechanical properties of the construct in the absence of any biological healing or remodeling. In vivo studies are necessary to investigate the biological behaviour of these fixation techniques. Although none of the LARS devices showed any visible signs of damage after the testing, the response of the device to in vivo forces over longer periods of time remains unknown.

Conclusions

Our findings suggest that biomechanical secure fixation of the LARS for ACL reconstruction can be achieved using either biodegradable or titanium interference screws. Furthermore, the stability of the fixation is independent of the type of approach, type of investigation, and whether extra-articular outside-in or intra-articular inside-out fixation is used.

References

1. Brand J, Weiler A, Caborn DNM, Brown CH, Johnson DL (2000) Graft fixation in cruciate ligament reconstruction. Am J Sports Med 28(5):761–764
2. Brand JC, Nyland J, Caborn DNM, Johnson DL (2005) Soft-tissue interference fixation: bioabsorbable screw versus metal screw. Arthroscopy 21(8):911–916
3. Brown CH, Wilson DR, Hecker AT, Ferragamo M (2004) Graft-bone motion and tensile properties of hamstring and patellar tendon anterior cruciate ligament femoral graft fixation under cyclic loading. Arthroscopy 20(9):922–935
4. Ettinger M, Petri M, Haag KT, Brand S, Dratzidis A, Hurschler C, Krettek C, Jagodzinski M (2013) Biomechanical properties of femoral posterior cruciate ligament fixations. Knee Surg Sports Traumatol Arthrosc. doi:10.1007/s00167-013-2600-2
5. Ettinger M, Wehrhahn T, Petri M, Liodakis E, Olender G, Albrecht UV, Hurschler C, Krettek C, Jagodzinski M (2012) The fixation strength of tibial PCL press-fit reconstructions. Knee Surg Sports Traumatol Arthrosc 20(2):308–314
6. Frank CB, Jackson DW (1997) The science of reconstruction of the anterior cruciate ligament. J Bone Joint Surg Am 79(10):1556–1576

7. Hamido F, Misfer AK, Al Harran H, Khadrawe TA, Soliman A, Talaat A, Awad A, Khairat S (2011) The use of the LARS artificial ligament to augment a short or undersized ACL hamstrings tendon graft. Knee 18(6):373–378
8. Höher J, Möller HD, Fu FH (1998) Bone tunnel enlargement after anterior cruciate ligament reconstruction: fact or fiction? Knee Surg Sports Traumatol Arthrosc 6(4):231–240
9. Jagodzinski M, Ettinger M, Haasper C, Hankemeier S, Breitmeier D, Hurschler C, Krettek C (2010) Biomechanical analysis of press-fit fixation of anterior cruciate ligament transplants. Unfallchirurg 113(7):532–539
10. Kousa P, Jarvinen TLN, Vihavainen M, Kannus P, Jarvinen M (2003) The fixation strength of six hamstring tendon graft fixation devices in anterior cruciate ligament reconstruction: part I: Femoral site. Am J Sports Med 31(2):174–181
11. Morrison J (1970) The mechanics of the knee joint in relation to normal walking. J Biomech 3(1):51–61
12. Nagarkatti DG, McKeon BP, Donahue BS, Fulkerson JP (2001) Mechanical evaluation of a soft tissue interference screw in free tendon anterior cruciate ligament graft fixation. Am J Sports Med 29(1):67–71
13. Nau T, Lavoie P, Duval N (2002) A new generation of artificial ligaments in reconstruction of the anterior cruciate ligament. Two-year follow-up of a randomised trial. J Bone Joint Surg (Br) 84(3): 356–360
14. Newman SD, Atkinson HD, Willis-Owen CA (2013) Anterior cruciate ligament reconstruction with the ligament augmentation and reconstruction system: a systematic review. Int Orthop 37(2):321–326
15. Noyes FR, Barber-Westin SD (2001) Revision anterior cruciate surgery with use of bone-patellar tendon-bone autogenous grafts. J Bone Joint Surg Am 83-A(8):1131–1143
16. Nurmi JT, Jarvinen TL, Kannus P, Sievanen H, Toukosalo J, Jarvinen M (2002) Compaction versus extraction drilling for fixation of the hamstring tendon graft in anterior cruciate ligament reconstruction. Am J Sports Med 30(2):167–173
17. Weiler A, Hoffmann RF, Siepe CJ, Kolbeck SF, Suedkamp NP (2000) The influence of screw geometry on hamstring tendon interference fit fixation. Am J Sports Med 28(3):356–359
18. Weiler A, Windhagen HJ, Raschke MJ, Laumeyer A, Hoffmann RF (1998) Biodegradable interference screw fixation exhibits pull-out force and stiffness similar to titanium screws. Am J Sports Med 26(1):119–126
19. Yamamoto H, Ishibashi T, Muneta T, Furuya K, Mizuta T (1992) Effusions after anterior cruciate ligament reconstruction using the ligament augmentation device. Arthroscopy 8(3):305–310
20. Yasuda K, Tsujino J, Tanabe Y, Kaneda K (1997) Effects of initial graft tension on clinical outcome after anterior cruciate ligament reconstruction. Am J Sports Med 25(1):99–106
21. Zantop T, Weimann A, Schmidtko R, Herbort M, Raschke MJ, Petersen W (2006) Graft laceration and pullout strength of soft-tissue anterior cruciate ligament reconstruction: in vitro study comparing titanium, poly-d, l-lactide, and poly-d, l-lactide-tricalcium phosphate screws. Arthroscopy 22(11):1204–1210