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Does a combined screw and dowel construct improve tibial fixation during anterior cruciate ligament reconstruction?

Pierre Laumonerie^{1,5}  · Meagan E. Tibbo² · Gregoire Laumond^{3,4,5} · Dominique Barbier^{3,4} · Pauline Assemat⁴ · Pascal Swider⁴ · Franck Accadbled^{3,4}

Abstract

Purpose The aims of the present study were to compare the biomechanical properties of tibial fixation in hamstring-graft ACL reconstruction using interference screw and a novel combination interference screw and dowel construct.

Material and Methods We compared the fixation of 30 (2- and 4-stranded gracilis and semitendinosus tendons) in 15 fresh-frozen porcine tibiae with a biocomposite resorbable interference screw (Group 1) and a screw and dowel construct (Group 2). Each graft was subjected to load-to-failure testing (50 mm/min) to determine maximum load, displacement at failure and pullout strength.

Results There were no significant differences between the biomechanical properties of the constructs. Multivariate analysis demonstrated that combination constructs ($\beta = 140.20$, $p = 0.043$), screw diameter ($\beta = 185$, $p = 0.006$) and 4-strand grafts ($\beta = 51$, $p = 0.050$) were associated with a significant increase in load at failure. Larger screw diameter was associated with increased construct stiffness ($\beta = 20.15$, $p = 0.020$).

Conclusion The screw and dowel construct led to significantly increased fixation properties compared to interference screws alone in a porcine model. Increased screw diameter and utilization of 4-strand ACL grafts also led to improvement in load-to-failure of the construct. However, this is an in vitro study and additional investigations are needed to determine whether the results are reproducible in vivo.

Level of evidence Level V; *Biomechanical study*.

Keywords Anterior cruciate ligament · Tibial fixation · Interference screw · Biomechanical strength

Abbreviations

ACL Anterior cruciate ligament
BMD Bone mineral density

✉ Pierre Laumonerie
laumonerie.pierre@hotmail.fr

¹ Department of Orthopaedics, Hôpital Pellegrin, 33000 Bordeaux, France

² Department of Orthopedic Surgery, Mayo Clinic, Rochester, MN, USA

³ Department of Orthopaedics, Children's Hospital, CHU de Toulouse, Toulouse, France

⁴ IMFT UMR CNRS 5502, University of Toulouse, CHU de Toulouse, Toulouse, France

⁵ Present Address: Place du Docteur Baylac, 31059 Toulouse, France

Introduction

Anterior cruciate ligament (ACL) reconstruction is one of the most commonly performed orthopedic procedures, with more than 100,000 being performed annually in the USA [2]. Stable graft fixation is critical during the early rehabilitation phase of anterior cruciate ligament (ACL) reconstruction to avoid graft elongation and failure. The tibial fixation site is mechanically the weakest point, due to the reduced bone mineral density (BMD) of the tibial metaphysis [5, 29]. Additional hypotheses suggest that the angle at which the forces are applied to the tibial graft also contributes to decreased pullout strength [5, 11].

Evidence-based selection of a tibial fixation construct remains challenging due to limited clinical data, as well as variability in outcomes reporting and surgical technique. To date, interference screw fixation is one of the most commonly utilized fixation techniques for soft tissue grafts [17]. However, there is no consensus with respect to the

clinical superiority of one cortical suspension device compared to another for ACL reconstruction. Those that have compared various methods of tibial fixation have demonstrated no differences in clinical outcomes [18, 22].

Depending on the series, interference screws [11], screw and washer fixation [13, 24], stirrups [13], suspension button [25] or a combination of these [1] have all been linked to superior biomechanical tibial fixation. However, the current literature lacks a robust biomechanical comparison of interference screws and combination of screw and dowel devices with a similar insertion technique [1]. The aims of the present study were to compare the biomechanical properties of tibial fixation in hamstring-graft ACL reconstruction using interference screw and a novel combination interference screw and dowel construct (Amplitude, France; Biomatlante, France). Intratunnel tibial fixation was assessed via tensile load-to-failure. We hypothesized that the combined screw and dowel construct would provide improved tibial fixation properties compared to screws alone in a porcine model.

Methods

Two soft tissue tibial tunnel fixation devices were biomechanically evaluated utilizing load-to-failure testing. We assessed a biocomposite resorbable interference screw *OSTEOTWIN* (Biomalante, France) and a screw

and dowel construct *ECLIPSE BCP* (Biomalante, France) (Fig. 1).

Specimen preparation

Testing was performed on 15 fresh-frozen mature porcine tibias (Lyon, France). The porcine model was selected because prior studies have reported similar biomechanical properties to that of the young adult human knee [26, 31]. A total of 30 fresh cadaveric gracilis and semitendinosus tendons were harvested from 15 cadavers at our university's anatomy laboratory (Paul Sabatier University, Toulouse, France). Specimens were stored at -20 °C. Two- ($n=12$) and four ($n=15$)- strand grafts were created and adjusted to 7, 8 or 9 mm in diameter with a graft sizing block. Those that were smaller than 7 mm were excluded, and those that were larger than 9 mm were trimmed in line with the fiber orientation. The 27 grafts were assigned to 2 groups; interference screw fixation only (Group 1, $n=12$), and screw and dowel fixation (Group 2, $n=15$).

Description of fixation methods

All grafts were inserted by a single surgeon (GL) according to the manufacturers' specifications. Screw diameter and the corresponding dowel and instrumentation size used are reported in Table 1. For each tibia, two tunnels were prepared using a tibial drill guide set at a 45° angle on either

Fig. 1 Tibial fixation devices included: **a** a biocomposite resorbable interference screw *OSTEOTWIN* (Biomalante, France) and **b** a sheath *ECLIPSE BCP* (Biomalante, France)

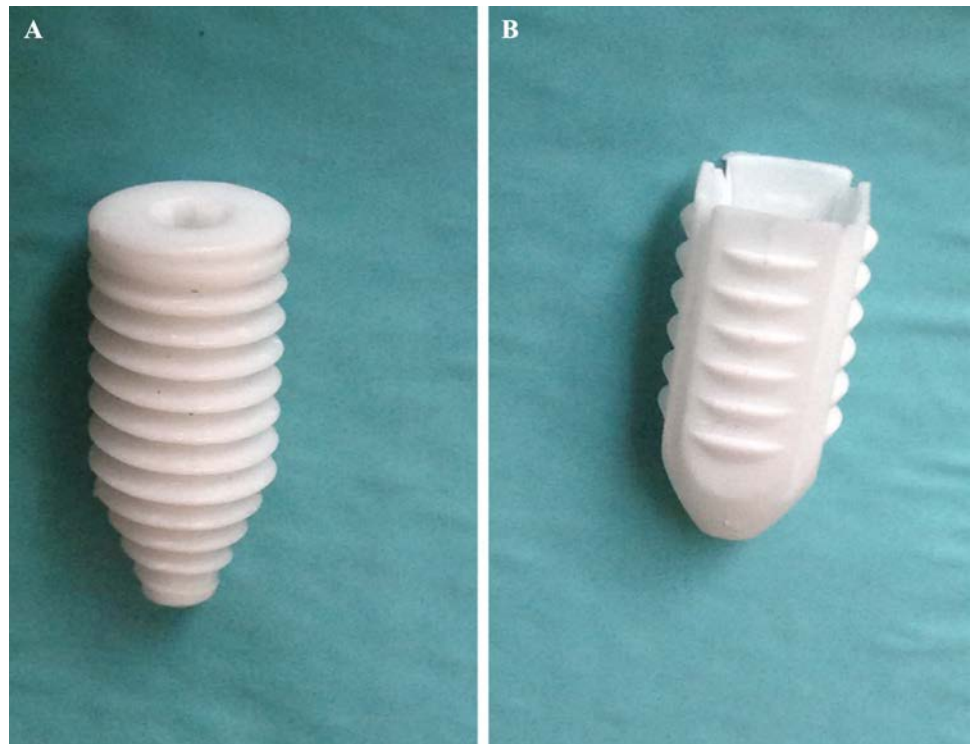


Table 1 Anterior cruciate ligament reconstruction tunnel, implant and instrumentation sizes

Tunnel diameter	Implant*		Instrumentation	
	Screw diameter	Dowel size	Dilator	Introducer
7	7	7/8	7/8	7/8
8	8	7/8	7/8	7/8
9	9	9/10	9/10	9/10

All dimensions are listed in millimeters

*Constant length 25 mm

side of the tibial tuberosity. The guide pin was advanced from the anteromedial proximal tibia through the footprint of the native ACL. The tibial tunnels were reamed to a diameter of 7, 8 or 9 mm (Table 1); the diameter of the reamer was selected based on the graft diameter (line-to-line fit). The graft was manually pulled through the tibial tunnel from distal to proximal until > 50 mm of the graft had advanced through the proximal aperture. During the entirety of the procedure, tension was manually applied to the graft distally and in line with the tunnel. For screw-only fixation, the tibial tunnel was tapped to allow insertion of the interference screw until it was flush with the cortical bone. For the combined dowel and screw fixation, a dilator was used to adjust the tunnel, and a corresponding sheath was introduced between the graft and the tibial tunnel. Finally, the screw was inserted flush with the cortical bone. The size of the screw was selected to match the diameter of the tunnel (7 × 25 mm, 8 × 25 mm or 9 × 25 mm).

Experimental apparatus

All screws were inserted with a torque meter (Chatillon® DFS2-R-ND with digital force sensor STS-0100, Ametek, Largo, Flo. the USA) in order to allow recording of the torque after insertion to 1/4, 1/2, 3/4, and at the completion of insertion. All grafts/fixation systems were subject to load-to-failure testing utilizing a dynamic load cell (Instron 3366; Instron Systems, Norwood, MA, the USA). The proximal 50 mm portion of the graft was looped over a 4.5 mm diameter stainless bar and mounted onto the dynamic load cell. After the application of a 10 N preload, the proximal tibia is held in place without the need for any further modification. This mounting system allowed the axis of the tibial bone tunnels to be collinear with the applied load (Fig. 2).

Load-to-failure tests

Parameters for tensile load-to-failure testing protocol were selected after the literature search and synthesis of common parameters from the various protocols [16, 30, 32].

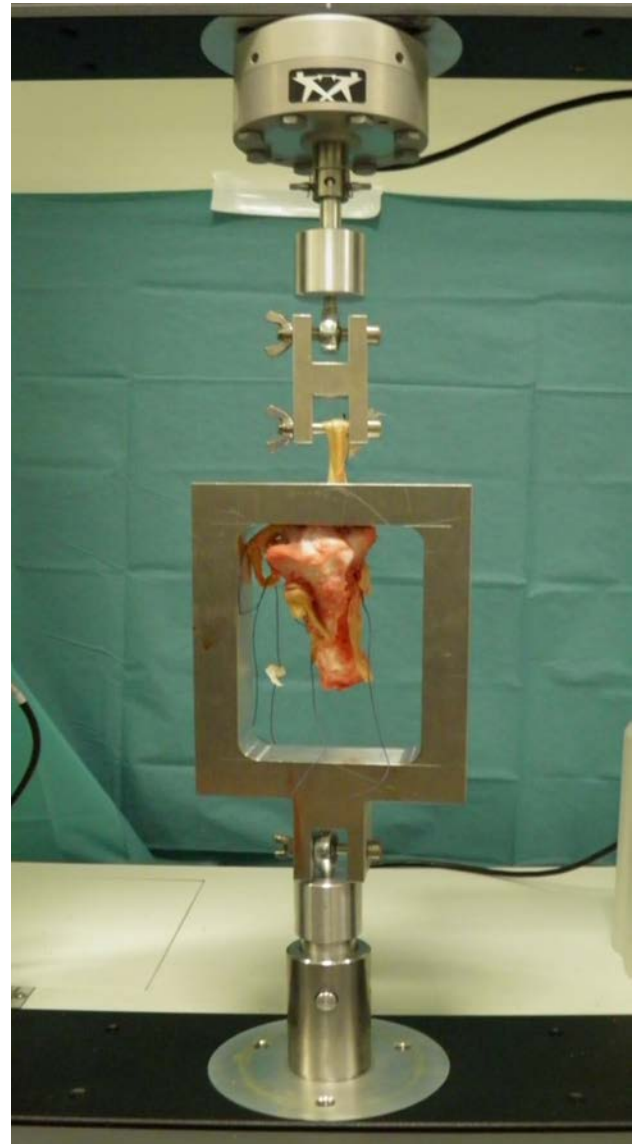


Fig. 2 Biomechanical testing setup utilizing a dynamic load cell device (Instron 3366; Instron Systems, Norwood, MA, USA), which allowed for the force vector to be applied in line with the tibial tunnel on the four-strand graft fixed with screw and sheath construct

As a result, the graft was first preloaded with a constant 10-N tensile force to allow for system accommodation [1]. After the preloading protocol, grafts were further displaced at 50 mm/min until failure [1] to simulate a sudden overload event at the knee. Biomechanical parameters including load at failure (N), displacement at failure (mm) and pullout stiffness (N/mm) were measured. Displacement at failure was measured as the total elongation at ultimate failure and accounted for tendon elongation, graft slippage or tearing and device pullout. Stiffness was calculated from the same linear portion of the load-elongation curves from the load-to-failure raw data. The mechanism

(e.g., grafts slippage, graft tear, device pullout or ligaments peeled off from their insertions) and the site of failure were also observed and recorded.

Statistical analysis

Descriptive statistics (mean with standard deviation for continuous variables and frequencies with proportions for categorical data) were used to summarize recorded variables. Wilcoxon rank sum (nonparametric test) tests were used to assess univariate differences between screw-only and combined screw and dowel groups. In order to discern the effect of the device, the screw diameter, number of graft strands, displacement at failure and stiffness were corrected for in the multivariable linear regression model. P values less than 0.05 were considered statistically significant. Statistical analysis was conducted using R (version 3.3.2, R Core Team 2013. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria).

Results

Results from the load-to-failure testing and p values for univariate comparisons between Groups 1 and 2 are reported in Table 2. The mean ultimate load at failure and stiffness were 515 N (SD 122.98) and 70.5 N/mm (SD 22.16) with screws and dowels, respectively. The mean ultimate load at failure and stiffness were 336.5 N (SD 153.24) and 55.1 N/mm (SD 20.18) with screws alone. The univariate comparisons revealed no significant difference between screws alone and combined devices.

Multivariable analysis (Table 3) demonstrated that the use of combined fixation with screws and dowels ($\beta=140.20$ (95% CI 5 to 297), $p=0.043$), screw diameter ($\beta=185.05$ (95% CI 61 to 309), $p=0.006$) and 4-strand grafts ($\beta=51.00$ (95% CI 7 to 187), $p=0.050$) was associated with a significant increasing in ultimate load at failure. The increased screw diameter was also associated with increased construct stiffness ($\beta=20.15$ (95% CI 4 to 37), $p=0.020$).

There were no differences between devices with respect to the mode of failure. Recorded failure modes were graft

Table 2 Results of load-to-failure testing and p values from univariate comparisons between devices

Variable	Screws			Screws and dowels			p value*
	<i>Ove</i>	<i>D.S</i>	<i>Q.S</i>	<i>Ove</i>	<i>D.S</i>	<i>Q.S</i>	
	n=12	n=6	n=6	n=15	n=6	n=9	
Torque tightening Nm, mean (SD)							
1/4	0.66 (0.21)	0.58 (0.20)	0.75 (0.21)	0.87 (0.21)	0.813 (0.31)	0.95 (0.04)	0.35
2/4	0.85 (0.22)	0.89 (0.25)	0.80 (0.19)	1.11 (0.22)	1.01 (0.43)	1.18 (0.16)	0.52
3/4	1.07 (0.36)	1.08 (0.32)	1.06 (0.46)	1.53 (0.36)	1.43 (0.44)	1.40 (0.34)	0.52
4/4	1.09 (0.37)	1.35 (0.37)	0.84 (0.09)	1.64 (0.37)	1.81 (0.49)	1.64 (0.65)	0.53
Ultimate load at failure N, mean (SD)	336.5 (153.24)	260 (72.21)	413 (103)	515 (122.98)	440.83 (134)	565 (101.08)	0.32
Displacement at failure mm, mean (SD)	4.16 (3.2)	5.72 (1.90)	2.61 (1.44)	3.33 (1.24)	3.65 (1.26)	3.08 (1.65)	0.26
Stiffness N/mm, mean (SD)	55.1 (20.18)	52.6 (14.10)	57.6 (20.1)	70.46 (22.16)	65.9 (19.11)	73.5 (21.94)	0.51

Ove., Overall, *D.S.*, and *Q.S.*, Double strand, and quadruple strand

*Comparisons between the overall result of screws alone and combined devices (screws and dowels)

Table 3 Results of multivariable linear regression analysis

Variables	Ultimate load at failure		Displacement at failure		Stiffness	
	β -Coef (95% IC)	p value	β -Coef (95% IC)	p value	β -Coef (95% IC)	p value
<i>Devices</i>						
Screw	Reference		Reference		Reference	
Screw and dowel	140 (5 to 297)	0.043	- 0.4 (- 2.71 to 1.95)	0.74	20.2 (4 to 37)	0.020
Screw diameter	185 (61 to 309)	0.006	- 0.5 (- 2.7 to 1.7)	0.63	6.4 (- 12 to 24)	0.465
<i>No. of graft strands</i>						
Double	Reference		Reference		Reference	
Quadruple	51 (7 to 187)	0.050	- 1.5 (- 3.9 to 0.84)	0.19	0.3 (- 16 to 17)	0.970

p values in bold are statistically significant

tears in 13 cases, ligaments peeled off from their tibial insertions in 13 cases, and tibial plateau fracture in 1 case in Group 2.

Discussion

Based on the results of the present study, fixation obtained using a screw and dowel construct led to a significant increase in biomechanical properties compared with interference screws alone, in a porcine ACL reconstruction model.

Multivariate analyses in the present study showed that the addition of a dowel to the interference screw was associated with a significant increase in ultimate load-to-failure ($\beta = 140$, $p = 0.043$) and stiffness ($\beta = 20$, $p = 0.020$). Combination devices were hypothesized to improve biomechanical properties by separating limbs of the graft, ensuring concentric placement of the screw, and providing homogeneous friction between the tendon and tibial metaphyseal bone [1, 11]. Combination fixation could also improve fixation characteristics by increasing radial force and compression on the graft against the tunnel wall [1, 11]. While Kousa et al. [20] found that the combination device provided significantly higher ultimate failure strength and decreased displacement compared with the other devices (i.e., interference screws and extracortical devices), Aga et al.'s [1] results showed that the combination of a screw and dowel did not consistently result in improved fixation characteristics compared to interference screw fixation alone. In fact, the authors [1] reported inferior fixation among combination devices. We posited that differences in insertion technique [31, 32], screw length [7, 32], surgical technique [35] and number of graft strands [12, 16] likely contributed to the significant variability of biomechanical properties described in the literature.

The screws and dowels were inserted according to the manufacturers' recommendations. We performed tunnel dilations in addition to simple tunnel reaming to create impaction of the surrounding cancellous bone and increase tunnel wall bone volume, in an effort to increase fixation strength [15]. Although Cain et al. [8] demonstrated a beneficial effect of dilation on fixation properties in cadaveric bones, Rittmeister et al. [28] did not report any significant improvement in young human cadaveric specimens. According to Dunkin et al. [10], the reduced effect of dilatation on fixation in younger patients' tibiae is likely associated with higher bone mineral density and may explain the conflicting results in the literature.

Our data suggest that the 4-stranded grafts ($\beta = 51$, $p = 0.05$) had significantly higher ultimate load-to-failure compared to 2-stranded grafts. Hamner et al. [17] demonstrated that there was a strong positive linear correlation between maximum failure load and the cross-sectional area for 1-strand, and equally tensioned 2- and 4-strand hamstring

tendon grafts. Boniello et al. [4] reported similar findings. However, Hamner et al. [17] also highlighted that applying unequal tension graft strands led to significantly lower failure loads for a given cross-sectional area. The authors of the aforementioned studies [4, 17] posited that the lower revision rates associated with larger diameter hamstring tendon grafts were due to the fact that these grafts are stronger. While most published biomechanical studies compared various devices using 4-stranded grafts, the influence of the number of graft strands on tibial fixation could explain the lack of significant differences between fixation devices in our study and others.

The choice of the screw diameter employed in this study was determined by the tunnel diameter, which was in turn dictated by the size of the prepared graft (Table 1). We found that increased screw diameter was correlated with an increased ultimate load-to-failure. However, results in the literature are mixed with respect to the effect of screw diameter and length on fixation properties. A biomechanical study by Weiler et al. [32] analyzed the effect of varying screw diameter as well as lengths on graft fixation. Their results suggested that screw length had a greater impact on fixation strength than screw diameter. They did, however, recommend oversizing the screw by 1 mm (with respect to the tunnel size) due to concern for graft slippage. Two studies evaluating graft slippage showed similar findings with no difference between 7- and 9-mm screws [31].

Limitations

The present study is not without limitation. The results achieved in an in vitro biomechanical animal model cannot be directly transferred to a clinical setting. Second, we did not perform cyclic load-to-failure testing which would likely provide more physiologically relevant data. Third, the screws and dowels utilized in the present study were resorbable biocomposite and the extent to which the biomechanical properties degrade over time was not assessed. And lastly, differences in biomechanical properties may also have been influenced by testing setup. Woo et al. [33] found that specimen age and graft orientation had a significant influence on the structural properties of the human ACL. Age-related decreases in ACL linear stiffness, ultimate load-to-failure and energy absorbed at failure have also been demonstrated. Furthermore, a higher percentage of ligament insertional avulsions have been reported among ACLs tested in the tibial orientation (i.e., tensile load applied along the axis of the ACL in the line with the tibial insertion site) (Fig. 2) compared to the anatomic orientation (i.e., Tensile load applied along the axis of the ACL, while the normal anatomical angle of the ACL insertion to the bone was preserved) [33]. These data may explain the large decrease in ACL fixation properties in the present series compared to studies using

young human tissue tested in an anatomic orientation [24]. These data further highlight the importance of a constant test setup in an effort to reduce the impact of confound orders on the biomechanical model. In the same vein, future studies should utilize consistent insertion technique and tissues with the consistent or measurable internal by mechanical properties in an effort to isolate the effect of a single fixation modality.

Conclusions

In conclusion, the addition of a dowel improves biomechanical properties of tibial fixation of hamstring grafts in a porcine ACL reconstruction model. Larger diameter graft also improved fixation properties including ultimate load-to-failure.

Author contribution PL contributed to data analysis and interpretation, critical revisions, manuscript review, statistical analysis. MET was involved in data analysis and interpretation, critical revisions, manuscript review. GL and DB contributed to data acquisition. PA was involved in data acquisition, study design, data analysis and interpretation, critical revisions, manuscript review, administration, technical and material support. PS and FA contributed to study design, data analysis and interpretation, critical revisions, manuscript review, administration, technical and material support, study supervision.

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Disclosures

Conflict of interest The authors report no conflicts of interest with respect the materials or methods used in this study or the findings specified herein.

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