1	Anterior Cruciate Ligament Reconstruction Is Associated With Greater Tibial Tunnel
2	Widening When Using A Bioabsorbable Screw Compared To An All-Inside
3	Technique With Suspensory Fixation
4	
5	ABSTRACT
6 7	Purpose:
8	To compare clinical outcomes and tunnel widening following anterior cruciate
9	ligament reconstruction (ACLR) performed with an all-inside technique (Group A) or
10	with a bioabsorbable tibial screw and suspensory femoral fixation (Group B).
11	Methods:
12	Tunnel widening was assessed using computed tomography (CT) and a previously
13	validated analytical best fit cylinder technique at approximately one-year following
14	ACLR. Clinical follow up comprised evaluation with IKDC, KSS, Tegner, Lysholm
15	scores, and knee-laxity assessment.
16	Results: The study population comprised twenty-two patients in each group with a
17	median clinical follow up of 24 months (range 21 to 27 months). The median duration
18	between ACLR and CT was 13 months (range 12 to 14 months). There were no
19	significant differences in clinical outcome measures between groups. There were no
20	differences between groups with respect to femoral tunnel widening. However, there
21	was a significantly larger increase in tibial tunnel widening, at the middle portion, in
22	Group B (2.4 ± 1.5 mm) compared to Group A (0.8 ± 0.4 mm) (p=0.027), and also at
23	the articular portion in Group B (1.5 \pm 0.8mm) compared to Group A (0.8 \pm 0.8mm)
24	(p=0.027).
25	Conclusion: Tibial tunnel widening after ACLR using hamstring tendon autograft is

26 significantly greater with suspensory femoral fixation and a bioabsorbable tibial

27	interference screw when compared to an all-inside technique at a median follow up of
28	two years. The clinical relevance of this work lies in the rebuttal of concerns arising
29	from biomechanical studies regarding the possibility of increased tunnel widening
30	with an all-inside technique.
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34 35	Key Terms: All-Inside; ACL reconstruction; Tunnel widening; Bioabsorbable Screw; Retrograde
36	drilling
37	Level of evidence: Level III
38	
39	Introduction
40	In 1995, Morgan et al first described all-inside anterior cruciate ligament
41	reconstruction (ACLR) using both tibial and femoral sockets, and the avoidance of
42	drilling complete tunnels. Although there are now many variations of all-inside
43	ACLR, recent systematic review has demonstrated that the overall strategy is
44	associated with low graft failure rates and significant improvements in clinical
45	outcomes with respect to knee function, pain, stability, and patient satisfaction at short
46	term follow-up. However, there are only a small number of comparative studies
47	[8,17,23] and therefore the proposed benefits over standard techniques remain
48	unproven. One of the theoretical benefits is a decrease in the incidence of tunnel
49	widening (TW) [12]. This is a phenomenon that frequently occurs after ACLR,
50	particularly with hamstring tendon grafts. It is reported to occur predominantly in the
51	first 6 weeks after surgery. The main clinical concern with tunnel widening is that in

52 the event of graft failure, enlargement of tunnels can compromise single stage 53 revision ACLR, and result in the need for bone grafting and a two stage procedure. 54 The pathophysiology of tunnel widening is multifactorial. Mechanical, surgical and 55 biological factors have all been implicated in the etiology [4,5,16,28]. However, the 56 interaction between factors is not completely understood and for this reason, the rate 57 of tunnel widening after ACLR must be specifically evaluated for different variations 58 of surgical technique. To the knowledge of the authors only one previous study has 59 specifically evaluated tunnel widening after all-inside ACLR in a comparative study. 60 Mayr et al demonstrated that femoral tunnel widening after all-inside ACLR using 61 suspensory fixation, was significantly greater than following ACLR with aperture 62 fixation with interference screws for both tibial and femoral tunnels [18]. Although 63 the latter is a frequently used technique, a multi-national registry based review of 64 contemporary practice reveals that in Denmark, Norway, Sweden and the UK the 65 most popular graft choice is hamstring tendon autograft fixed with an interference 66 screw on the tibia and suspensory femoral fixation [25]. The aim of this study was 67 therefore to compare tunnel widening following this technique against all-inside 68 ACLR. The study hypothesis was that a significantly greater degree of tibial tunnel 69 widening would be observed with the all-inside technique when compared to ACLR 70 fixed with an interference screw on the tibia and suspensory femoral fixation.

71

72 Materials and Methods

73 Institutional review board approval from University of Rome La Sapienza was74 granted for the study.

75 Patients who underwent hamstring tendon autograft ACLR for a chronic ACL rupture

76 (>3 months from the date of injury) with either the graftlink all-inside technique [14]

or with suspensory femoral fixation and a tibial interference screw between January
2016 and June 2016 were considered for study eligibility. Patients were excluded if
they had sustained a multi-ligament injury, or had a Segond fracture, but patients with
meniscal and/or chondral injuries were included. Further exclusion criteria were a
history of previous knee injury/surgery, patients aged over forty years and those with
a body mass index (BMI) greater than thirty. Informed consent was obtained from all
patients.

84

85 Surgical Technique

86 For both surgical techniques, the tunnels were drilled corresponding to graft diameter. 87 The femoral tunnel center was located at approximately 40% of the proximal-to distal 88 distance of the lateral notch and was centered between the lateral intercondylar ridge 89 and the posterior articular margin. This point was centered over the lateral bifurcate 90 ridge at a distance equivalent to the planned tunnel radius, plus an additional 2.5mm 91 from the posterior articular cartilage. The center of the tibial tunnel was located at 92 40% of the medial-to lateral width of the interspinous distance, in line with the 93 posterior edge of the lateral meniscal anterior horn, approximately 15 mm anterior to 94 the posterior cruciate ligament [1].

95 Group A: All inside ACLR

In the all-inside group patients underwent ACL reconstruction performed with the
graft-link technique [14]. The harvested semitendinosus tendon was quadrupled to
obtain a final graft length of no more than 75mm, and sewn in linkage with a
TightRope-RT adjustable loop cortical button (Arthrex, Naples, FL) and a high
strength suture (No. 0 FiberWire; Arthrex, Naples, FL) on each side of the graft.

101 Standard anterolateral (AL) and anteromedial portals were used. With a standard

102 guide set at 60-65°, a 25mm tibial socket was created at the anatomic ACL insertion

103 point using a specific retrodrill (Flipcutter, Arthrex, Naples, FL). A 25mm femoral

104 socket was created with an outside-in technique using a standard guide set

- approximately 100 to 110° and the same retrodrill as on the tibial side. Using a shuttle
- suture on both sides, the graft was introduced into the knee through the AM portal and
- 107 fixed first on femoral side, then on tibial side with the "flip-then-fill technique" [14].
- 108
- 109 *Group B: Femoral suspensory fixation and tibial interference screw.*

110 Patients underwent ACLR with an outside-in technique and doubled semitendinosus

and gracilis tendons (DGST) autograft. The tibial tunnel was drilled over a wire that

112 was placed in the anatomic tibial ACL insertion point using the Arthrex footprint

113 guide set at 60-65° with a standard anterograde drill. On the femoral side, a 25 mm

bone socket was drilled with an outside-in technique and using the Arthrex footprint

115 guide with drill sleeve set at approximately 100 to 110° employing a Flipcutter

- 116 retrodrill (Arthrex, Naples, USA). The graft was then passed fixed with an adjustable
- 117 loop length device on the femur (TightRope-RT Arthrex, Naples, FL) and an
- absorbable interference screw (Deltascrew, Arthrex, Naples, FL), sized 1 mm greater
- than graft diameter, on the tibia.
- 120 Postoperative rehabilitation

121 All patients were placed in an extension brace for 2 weeks. Isometric exercises were

122 commenced on the second postoperative day and patients were encouraged with

123 progressive weight bearing as tolerated. After 2 weeks, the brace was removed and an

- 124 emphasis placed on regaining full range of motion. Cycling and swimming were
- 125 permitted from 4 weeks onwards. Patients participated in progressive functional

activities including running at 3 months and a return to sport specific training at 6-8months after surgery.

128 Postoperative Clinical Evaluation

129 As part of the standardized follow-up for ACLR at our institution, all patients

130 underwent standard knee ligament examination, specifically including an evaluation

131 of Lachman's test, side-to-side laxity difference testing using a knee laxity-testing

132 device (KT-1000;MEDmetric, San Diego, CA) and the pivot-shift test. The Lachman

133 test was graded as negative (normal anterior-posterior translation with a firm end

point), positive 1+ (increased anterior-posterior translation as compared with the

135 contralateral side with a firm end point) and positive 2+ (increased anterior-posterior

translation as compared with contralateral side with no firm end point). The pivot-

shift test was graded 0 (negative), 1 (glide), 2 (jerk), 3 (subluxation) [10]. In addition,

138 the IKDC Knee Examination Form, Knee Society Score (KSS) for pain and function,

and Tegner and Lysholm scores were recorded pre-operatively and at-final follow up.

140

141 Radiological evaluation

142 All patients underwent post-operative CT to assess tunnel widening at approximately 143 1 year following ACLR. [16] A 16-slice MSCT scanner Philips MX 8000 with post-144 process multislab reconstruction on sagittal and coronal planes (slice thickness 1 mm, 145 retrorecons 0.75 mm) was used for the evaluation. Scanning was performed from a 146 level just above the femoral tunnel to a level below the external aperture of the tibial 147 tunnel. The CT images were exported to an image analysis software (Mimics v1.6, 148 Materialise, Leuven, Belgium) and a manual segmentation of the bone structures, 149 bone tunnels and fixation devices was performed using bone-soft tissue density 150 variation. The segmentation process relies on using bone-soft tissue density variation

151	on CT images, adjusting a density range to highlight bone anatomy on CT scan
152	images. Manual revision of the CT images was performed to correct errors, and assure
153	that the outline of the bone and tunnels were appropriately filled. This allowed the
154	creation of a specific 3D bone model of the knee joint for all patients. [Fig.1a,b].
155	Tunnel diameter was evaluated using the best fit cylinder technique reported in detail
156	by Crespo et al. who used the Mimics v1.6, Materialise software, that allows an
157	analytical cylinder to be fitted to the 3D cast of the entire tunnel length and then
158	measured [Fig.2a-c]. This method was selected because Crespo et al [3] demonstrated
159	that this method provided a high correlation with the drill sizes used, demonstrated
160	high inter-rater agreement concluded that this was the best method to evaluate ACL
161	tunnel size in a 3D model. Moreover, it has previously been validated, and has
162	demonstrated high intraobserver and interobserver reliability and accuracy (Intraclass
163	correlation coefficient (95% CI): 0,745 [0.553-0.862] and intra-rater agreement (ICC
164	[95% CI]) were totally automated, with total agreement (ICC of 1.00) [3,26].
165	In the tibial tunnel of Group B, careful attention was paid to the position of the
166	interference screw: when the screw head was found to protrude from the bone tunnel
167	[Fig.3 a,b], thereby artificially enlarging the diameter of the best-fit cylinder, in order
168	to avoid this bias, a line of the tunnel border was drawn through the screw. To assess
169	changes in tunnel widening in both groups, the diameters of the tunnels measured at
170	follow-up (T1) were compared with the diameter of the drill used at surgery (T0) in
171	each patient.
172	Statistical analysis

173 Statistical analysis generated standard descriptive statistics: means, standard

deviations, and proportions. The Wilcoxon test was used to evaluate differences

between pre-operative and follow-up results in each group. The Mann-Whitney U test

176 was applied to verify differences between the two groups. Statistical significance was 177 set at P< 0.05. The Statistical Package for Social Sciences (SPSS) software version 22 178 was used for all calculations. A sample size calculation for a continuous outcome 179 superiority trial was performed using the sealedenvelope.com online based software 180 and published tunnel widening data from Mayr et al [18]. This demonstrated that forty 181 patients were required in order to have a 90% chance of detecting, as significant at the 182 5% level, an increase in the primary outcome measure from $111.1\% \pm 10.8\%$ (tibial 183 tunnel widening reported by Mayr et al [18] with an interference screw) in the control 184 group to 122.4% (tibial tunnel widening with an all-inside technique) in the 185 experimental group. 186 187 Results The overall study population comprised of forty-four patients (twenty-two in each 188 189 group) who underwent ACLR for a chronic ACL injury. The mean time between 190 injury and surgery was 8 months (range 5 to 13 months). The median duration of 191 clinical follow up after ACLR was 24 months (range 21 to 27 months). The median 192 duration of time between ACLR and post-operative CT evaluation was 13 months 193 (range 12 to 14 months). 194 The baseline characteristics of the two groups are shown in Table.1. 195 No significant differences were detected between the two groups with respect to any 196 of the clinical or patient reported outcome measures assessed. This information is 197 summarized in Tables 2 and 3. 198

199 Radiological evaluation

200	Tunnel widening data is summarized in Table 4. In group A, the mean drill diameter
201	at T0 was 9.3 \pm 0.5. This was significantly increased at T1 by 30% to a mean femoral
202	tunnel diameter of 12.1 \pm 0.9 mm at the middle portion (p=0.02), and by 28% to a
203	mean diameter of 12 ± 1.7 mm at the articular portion (p=0.04). The mean tibial tunnel
204	diameter was increased at T1 by 8% to 10.1 ± 0.6 mm at the middle portion (n.s.) and
205	significantly increased by 9% to 10.1 ± 1 mm at the articular portion (p=0.02).
206	
207	In group B, the mean drill diameter at T0 was 8.6±0.5. This was significantly
208	increased at T1 by 23% to a mean femoral tunnel diameter of 10.6 ± 1.2 mm at the
209	middle portion (p=0.01) and by 25% to 10.8 ± 1 mm at the articular portion (p=0.01).
210	The mean tibial tunnel diameter increased significantly by 27% to 11.1 ± 1.6 mm at
211	the middle portion (p=0.01) and 17% to 10.1 ± 1.2 mm at the articular portion
212	(p=0.02).
213	
214	The differences in tunnel widening between groups is summarized in Table 5. No

215 differences were found between groups with respect to femoral tunnel widening.

216 However, there was a significantly larger increases in tunnel widening on the tibial

217 side, at the middle portion, in Group B (2.4 \pm 1.5mm) compared to Group A (0.8 \pm

218 0.4mm) (p=0.027), and also at the articular portion in Group B (1.5 ± 0.8 mm)

compared to Group A (0.8 ± 0.8 mm) (p=0.027). 219

220

221 Discussion

The main findings of this study were that tibial tunnel widening was significantly 222

223 greater following ACLR performed with femoral suspensory fixation and a tibial

224 interference screw fixation when compared to the all-inside technique and that there was no significant differences between groups with respect to femoral tunnelwidening or clinical outcomes.

227

228 The potential reasons for the differences between groups with respect to tibial tunnel 229 widening can be considered with respect to biomechanical and biological issues 230 respectively. It is recognised that tunnel widening is greater with hamstring tendon 231 grafts when compared to BTB and also that most tunnel widening occurs in the first 6 232 weeks after surgery. This suggests that reducing the time to graft to bone healing, by 233 improving the biological enivronment, may reduce the extent of tunnel widening. 234 Bone ingrowth has been reported to be slowest at the tunnel apertures and this may be 235 a result of the "synovial bathing effect" [27]. It is postulated that retrograde drilling 236 may reduce this effect because it is associated with less subchondral bone 237 fragmentation as well as fewer fracture fragments at the tibial tunnel aperture 238 compared to anterograde drilling [19]. Retrograde drilling may therefore limit the 239 amount of synovial fluid migration from the joint to the bone tunnel [27]. This is 240 partly supported by Lanzetti et al [13] who reported that when using cortical 241 suspensory fixation, femoral sockets created using an outside-in technique were 242 associated with significantly less widening than those sockets created with a trans-243 tibial technique. Similarly, the use of a cortical adjustable loop-length device, which 244 allows complete filling of sockets by the graft may also reduce the empty space 245 available for synovial fluid migration [24]. 246 Suspensory fixation may offer other biological advantages over interference screw 247 fixation. Several authors have reported that interference screws provide a limited 248 tendon-bone contact area because much of the tunnel circumference is occupied by 249 the screw itself, while adjustable loop systems provide a greater contact zone [15,29],

250 and allow "four-zone direct graft healing" which has been associated in animal study 251 with the absence of tunnel widening on radiographic and histologic assessments [29]. 252 In contrast, from a biomechanical perspective it is suggested that extra-cortical 253 suspensory fixation may actually increase the risk of tunnel widening due to graft 254 micro-motion within the tunnels on the longitudinal axis (the "bungee cord effect") 255 and transverse axis (the "windshield wiper effect") [8]. This is therefore a concern 256 with the all-inside technique which uses two adjustable loop suspensory fixation 257 devices, particularly because of recent reports of loop lengthening with adjustable 258 suspensory fixation devices, which may result in increased graft micro-motion. 259 However, some recent biomechanical studies showed no significant loop lengthening 260 using two adjustable loop suspensory devices for femoral tibial fixation [21,22]. 261 Moreover, no evidence of increased tunnel widening was noted in this study with the 262 all-inside technique, when compared to a standard technique, and this allowed us to 263 reject the study hypothesis. 264 Bioabsorbable screws are also associated with other disadvantages. Despite their 265 widespread use, they are well recognized for their association with migration, cyst 266 formation, biological/immunological responses to the screw itself, and tunnel 267 widening [2,20]. However, to the knowledge of the authors, specific data on tunnel 268 widening with the bioabsorbable DeltaScrew (Arthrex, Naples, Florida) used for tibial 269 fixation, in association with suspensory femoral fixation, has not been published. It 270 should be emphasized that bioabsorbable screws should not be considered as a single 271 category because different biomaterial compositions may be associated with different degrees of tunnel widening. Karikis et al [11], in a study of patients undergoing 272 273 ACLR with interference screw fixation in both femoral and tibial tunnels 274 demonstrated a reduction in the tibial tunnel diameter at a mean follow up of 5 years

when a bioabsorbable screw was used (Matryx; ConMed Linvatec, Largo, FL). It is
not possible to determine whether the differences in tibial tunnel widening between
the current study and the findings of Karikis et al are due to the material properties of
the respective screws or due to difference in other aspects of the surgical technique,
including the femoral fixation or the length of follow-up.

280

There is a complex interplay of biomechanical and biological factors that influence tunnel widening after ACLR. Although the exact mechanisms though which tunnel widening occurred in the different groups in this study cannot be determined, it can be concluded that tibial tunnel widening in all-inside ACLR is significantly lower than in patients undergoing tibial fixation with a bioabsorbable screw. It could also be stated that the use of sockets instead of full tunnels confers preservation of bone for revision surgery but this was not specifically evaluated in the current study.

288

289 This study demonstrated excellent overall clinical results in both groups. However, it

is unlikely that it was adequately powered to detect a difference in clinical outcomes

between groups. Despite that it is important to highlight that the outcomes of ACLR

in the all-inside group showed excellent return to sport, knee stability, low graft

rupture rate and a high Lysholm, Tegner and IKDC score. This is in keeping with

other authors reporting the outcomes of all-inside ACLR.

295 This study has some limitations. The primary limitation was the retrospective design,

which has inherent limitations due to the risk of bias and confounding. However,

297 patients included in both groups were not significantly different demographically. The

assumption that the tunnel diameter at T0 was the same as the drill diameter used

299 could also be considered a limitation but this choice was determined by the reliability

300 between drill diameter and CT measurements in the early post-operative period 301 reported by previous authors [9,30], and the benefit of minimizing radiation exposure. 302 The overall study population was relatively small but this was based upon a sample 303 size calculation and inclusion of an adequate number of patients to evaluate tunnel 304 widening. A further limitation was that the median follow-up period was only two 305 years. This was considered to be appropriate because Fink et al [6] and Harris at al [7] 306 reported that most tunnel enlargement occurs within the first six weeks after surgery 307 and Mayr et al. [18] reported that the tunnels usually increased in size up to six 308 months postoperatively, and decreased slightly after a year.

309

310 Conclusions

311 Tibial tunnel widening after ACLR using hamstring tendon autograft is significantly

312 greater with suspensory femoral fixation and a bioabsorbable tibial interference screw

313 when compared to an all-inside technique at a median follow up of two years. The

314 clinical relevance of this work lies in the rebuttal of concerns arising from

biomechanical studies regarding the possibility of increased tunnel widening with an

all-inside technique.

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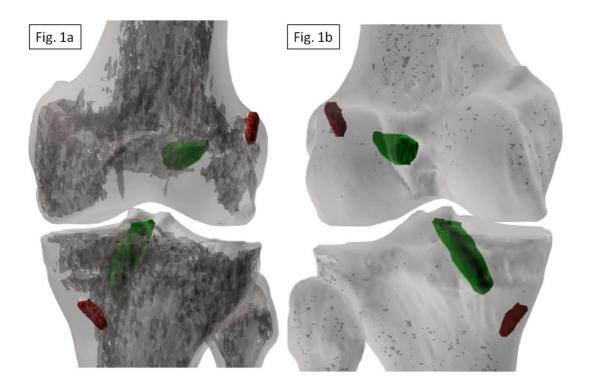


Fig. 1a,b. CT images of all patients were exported to an image analysis software (Mimics v1.6, Materialise, Leuven, Belgium) and a manual segmentation of the bone structures, bone tunnels and fixation devices was performed, allowing for the creation of a specific 3D bone model of the knee joint for all patient (1a, left knee, anterior view of an all inside technique; 1b, left knee, posterior view of an all inside technique; 1b, left knee, posterior view of an all inside

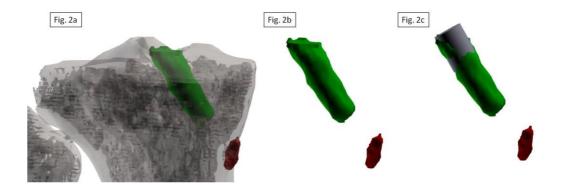


Fig. 2. A: right knee, 3D model of tibia, bone socket and fixation device of an allinside technique; B: right knee, 3D cast of tibial bone socket of an all-inside

technique; C: right knee, creation of an analytical best fit cylinder fitted to the 3D cast of the articular portion of the tibial bone socket of an all-inside technique.

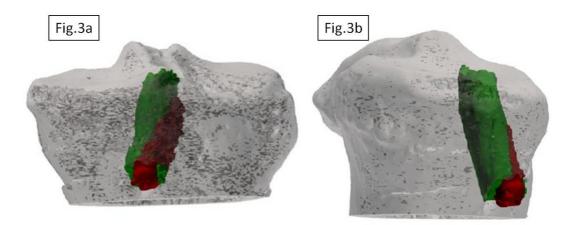


Fig. 3a,b. Left knee, screw protrusion from the tibial bone tunnel in the control group (3a, frontal view; 3b, lateral view).

Tab. 1 Baseline characteristics.

Variable	Group A	Group B	P value
		-	
Age	32.5±6.7	31.7±7.1	p>0.05
Sex (M;F)	15;7	17;5	p>0.05
Dominant side involvement	15	13	p>0.05
Time from diagnosis to intervention (months)	7.3±2	8.1±3.4	p>0.05
Meniscal lesions (Medial;Lateral)	2;3	2;4	p>0.05
Condral lesions (Femur;Tibia)	2;0	1;0	p>0.05

Tab. 2 Clinical Outcomes

Group A	Pre - op	Post - op	P value
Tegner score	7.2	6.6	p>0.05
Lysholm score	55.7 ± 9.4	97 ± 5.8	p=0.01
Kss for pain	59.8	95.6	p=0.01
Kss for function	75	100	p=0.01
IKDC	52.8	95.1	p=0.01
KT 1000	$9,5 \pm 2.4 \text{ mm}$	$1.75 \pm 1.2 \text{ mm}$	

Tab. 3 Clinical Outcomes			
Group B	Pre - op	Post - op	P value
Tegner score	7.1	6.6	P=0.02

KT 1000	10.1 ± 2.6 mm	2.1 ± 1.2 mm	
IKDC	53.4	94.9	p=0.005
Kss for function	75	100	p=0.005
Kss for pain	55.3	95.2	p=0.005
Lysholm score	55.9 ± 5.6	96.2 ± 3.3	p=0.005

Tab. 4 Radiological findings.	Tunnel widening from T0	(drill diameter) to T1 (follow-up)
		(,

Variable	Group A		P Value	Group B		P Value
	Т0	T1		Т0	T1	
Femoral middle portion*	9.3±0.5	12.1±0.9	0.02	8.6±0.5	10.6±1.2	0.01
Femoral articular portion*	9.3±0.5	12±1.7	0.04	8.6±0.5	10.8±1	0.01
Tibial middle portion*	9.3±0.5	10.1±0.6	0.07	8.6±0.5	11.1±1.6	0.01
Tibial articular portion*	9.3±0.5	10.1±1	0.02	8.6±0.5	10.1±1.2	0.01

*Data expressed as mean values ± standard deviation

Tab. 5 Radiological findings. Comparison between mean tunnel widening at T1 (follow-
up) of groups

Femoral side		Tibi	Tibial side		
∆ Middle	Δ Articular	∆ Middle	Δ Articular		

Group A *	2.7±1.2	2.6±1.6	0.8±0.4	0.8±0.8
Group B*	2.1±0.9	2.2±0.5	2.4±1.5	1.5±0.8
P Value	>0.05	>0.05	0.027	0.027

* Values expressed as difference (Δ) between tunnel diameter at T1 (follow-up) and at T0 (drill diameter) ;± standard deviation