Evaluation of a computer-assisted navigation system for anterior cruciate ligament reconstruction: Prospective non-randomized cohort study versus conventional surgery

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KEYWORDS
Anterior cruciate ligament reconstruction; Computer-assisted surgery

Summary
Background: Conventional reconstruction of the anterior cruciate ligament (ACL) is associated with a 15% failure rate. Computer-assisted navigation systems (CANS) have been developed to improve the accuracy of tunnel positioning.

Hypothesis: The use of a CANS for ACL reconstruction decreases the rate of failure, defined as IKDC grade C or D, compared to conventional ACL reconstruction.

Materials and methods: This prospective multicentre observational non-randomised open study compared two groups of patients requiring arthroscopic ACL reconstruction: one group was managed with a CANS and the other (control group) without a CANS. The primary evaluation criterion was based on the subjective and objective IKDC scores. Inclusion criteria were age older than 18 years and first ACL reconstruction procedure using autologous semitendinosus and gracilis tendons or an autologous bone-patellar tendon-bone graft. Of the 272 included patients, 214 were analysed; 100 were in the control group and 114 in the CANS group.
Introduction

Surgical reconstruction of the anterior cruciate ligament (ACL) is a very commonly performed procedure (about 40,000 cases per year in France). The goal is recovery of full knee function. Therefore, ligament reconstruction must be both anatomically and functionally optimal.

Good or very good overall objective and subjective outcomes have been reported in 85% of cases [1,2]. Failed reconstruction in the remaining 15% of cases is associated with an IKDC grade of C or D, an inability to resume previous occupation-related or sporting activities, and/or tunnel malposition. The result is loss of chance for the patient and additional healthcare costs related not only to the need for further surgery, but also to the well-documented meniscal and cartilaginous complications that characterise the natural history of ACL rupture.

Since the initial work by Julliard’s group [3,4], we have demonstrated that a computer-assisted navigation system (CANS) improves accuracy in positioning the femoral and tibial graft insertion sites. We therefore hypothesised that using a CANS significantly decreased the failure rate of ACL reconstruction.

To assess this hypothesis, we prospectively compared two groups of patients, an intervention group managed with CANS and a control group managed with conventional surgery. The primary evaluation criteria were the objective and subjective IKDC scores 1 year after surgery. A grade of A or B based on the IKDC scores was taken to indicate successful reconstruction and a grade of C or D failed reconstruction. Secondary evaluation criteria included the subjective IKDC score increase after 6 months and 1 year versus baseline, to determine whether the time to functional recovery was shorter in the CANS group; feasibility (percentage of patients actually managed with CANS in the CANS group); learning curve parameters (ligament positioning and operating time); and hospital stay characteristics (stay length, need for ICU admission, operating time, and immediate postoperative complications including reoperation). In addition, any complications after hospital discharge were recorded during three patient visits, 3 months, 6 months, and 1 year after the procedure. Finally, the time to resumption of physical activities was recorded, as well as the number and specific modalities of the rehabilitation sessions.

Materiel and methods

We used a prospective, observational, multicentre, comparative, non-randomised, open study design. The study was sponsored by the French Ministry of Health (National Health Program: Programme National de Soutien aux Innovations Techniques Coûteuses, Programme STIC 2005).

We included patients older than 18 years of age who were scheduled for a primary ACL reconstruction procedure using either the autologous semitendinosus and gracilis tendons (four-strand hamstring graft, FSHG) or an autologous bone-patellar tendon-bone graft (BPTB). All study data were handled confidentially and entered into an electronic case report form. Each patient was given an information sheet explaining how the data would be used and specifying the patient’s right to refuse the study and to access and modify the data. The primary evaluation criterion was assessed 1 year after ACL reconstruction.

We used the navigation system described by Julliard and Dessenne [3,5,6], with the Surgetrics Praxim station (Praxim Médiation, La Tronche, France) equipped with software dedicated to ACL reconstruction (ACL Logs).

The evaluation criteria were the objective and subjective IKDC scores, knee laxity measured using Telos radiography, and measurements of graft position.

Statistical methods

The statistical analyses were performed at the Grenoble Clinical Investigation Centre by an independent statistician who was blinded to the study data. To compensate for the absence of random patient allocation, two adjustment strategies were used: multivariate random-effects logistic regression and adjustment on a propensity score taking into account the main potential risk factors. Quality-of-life variables were analysed either one by one or in clusters reflecting dimensions derived from those in the SF-36 subscales, as the items were similar but not identical.

Results

Patients

Of 285 patients included initially, 13 were excluded (age < 18 years or previous ACL reconstruction); 58 (21.3%) of the remaining 272 patients were lost to follow-up, leaving 214 patients for the study (Fig. 1 and Table 1). As shown in Fig. 1, 114 patients were in the CANS group and 100 in the control group. The patients who were lost to follow-up were not significantly different from the study patients in terms of demographics or prognostic criteria.

For most of the demographic and clinical characteristics, no significant differences were found between the CANS and
ACL repair with versus without navigation

143 in the control group (conventional surgery)
- 7 patients included mistakenly
136 patients analysed
100 patients with the primary criterion at 12 months

142 in the CANS group (surgery with navigation)
- 6 patients included mistakenly
136 patients analysed
114 patients with the primary criterion at 12 months

Figure 1 Patient flow chart.

Table 1 Demographic and clinical features of the study patients before surgery.

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Navigation group</th>
<th>p value</th>
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<tbody>
<tr>
<td><strong>Demographics</strong></td>
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<tr>
<td>Age, mean ± SD (n)</td>
<td>28.9 ± 9.0 (n = 136)</td>
<td>31.0 ± 9.5 (n = 135)</td>
<td>0.060</td>
</tr>
<tr>
<td>Males, n/N (%)</td>
<td>95/136 (69.9%)</td>
<td>104/135 (77.0%)</td>
<td>0.181</td>
</tr>
<tr>
<td>BMI, mean ± SD (n)</td>
<td>23.6 ± 3.6 (n = 136)</td>
<td>24.2 ± 3.2 (n = 134)</td>
<td>0.139</td>
</tr>
<tr>
<td>Smokers, n/N (%)</td>
<td>51/134 (38.1%)</td>
<td>41/135 (30.4%)</td>
<td>0.574</td>
</tr>
<tr>
<td>High-level athlete, n/N (%)</td>
<td>23/134 (17.2%)</td>
<td>10/135 (7.4%)</td>
<td>0.015</td>
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<tr>
<td><strong>Medical history</strong></td>
<td></td>
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<tr>
<td>Overweight, n/N (%)</td>
<td>8/136 (5.9%)</td>
<td>12/134 (9.0%)</td>
<td>0.335</td>
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<tr>
<td><strong>Clinical evaluation</strong></td>
<td></td>
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<tr>
<td>Constitutional laxity, n/N (%)</td>
<td></td>
<td></td>
<td>0.285</td>
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<tr>
<td>Stiff/normal</td>
<td>126/136 (92.6%)</td>
<td>120/135 (88.9%)</td>
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<tr>
<td>Laxity</td>
<td>10/136 (7.4%)</td>
<td>15/135 (11.1%)</td>
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<tr>
<td>Alignment, n/N (%)</td>
<td></td>
<td></td>
<td>0.130</td>
</tr>
<tr>
<td>Varus</td>
<td>15/136 (11.0%)</td>
<td>26/135 (19.3%)</td>
<td></td>
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<tr>
<td>Normal</td>
<td>112/136 (82.4%)</td>
<td>98/135 (72.6%)</td>
<td></td>
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<tr>
<td>Valgus</td>
<td>9/136 (6.6%)</td>
<td>11/135 (8.1%)</td>
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<tr>
<td>Concomitant cartilage lesion, n/N (%)</td>
<td>15/125 (12.0%)</td>
<td>17/120 (14.2%)</td>
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<tr>
<td><strong>Type of graft, n/N (%)</strong></td>
<td></td>
<td></td>
<td>0.305</td>
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<tr>
<td>Autologous patellar tendon</td>
<td>53/133 (39.8%)</td>
<td>56/131 (42.7%)</td>
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<tr>
<td>Hamstring</td>
<td>78/133 (58.6%)</td>
<td>73/131 (55.7%)</td>
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<tr>
<td>Quadriceps tendon</td>
<td>2/133 (1.5%)</td>
<td>/</td>
<td></td>
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<tr>
<td>Other</td>
<td>/</td>
<td>2/131 (1.5%)</td>
<td></td>
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<tr>
<td>Subjective IKDC score, mean ± SD (n)</td>
<td>54.9 ± 15.4 (n = 128)</td>
<td>54.5 ± 17.3 (n = 126)</td>
<td>0.824</td>
</tr>
<tr>
<td><strong>Objective IKDC score (items 1-2-3), n/N (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>/</td>
<td>/</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>B</td>
<td>1/136 (0.7%)</td>
<td>1/135 (0.7%)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>90/136 (66.2%)</td>
<td>65/135 (48.1%)</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>45/136 (33.1%)</td>
<td>69/135 (51.1%)</td>
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control groups. However, differences were noted for high-level sports participation (17.2% in the CANS group versus 7.4% in the control group, \(P = 0.015\)) and the preoperative IKDC score (Table 1).

Only two quality-of-life items differed significantly between the two groups at baseline. Impairment of social activities due to physical and emotional problems was significantly less common in the CANS group than in the control group (53.2% versus 41.1%, \(P = 0.03\)). The vitality score was significantly higher in the CANS group (66.9 ± 18 versus 61.4 ± 20, \(P = 0.02\)).

### IKDC Scores

Mean time from study inclusion to the last follow-up evaluation (223 patients) was 386 days (range, 237–889 days) (Table 2). With neither of the two adjustment methods used was a significant difference found between the two groups for the proportion of patients whose IKDC grade was A or B (defining successful reconstruction): 91/100 (91%) in the control group and 104/114 (91.2%) in the CANS group, \(P = 0.953\). In the multivariate logistic regression model, the adjusted odds ratio (aOR) was 1.01 [0.36–2.84], \(P = 0.988\). The model was adjusted for the following potential confounders: centre effect, level of activity (high-level sports versus other), gender, constitutional baseline laxity, baseline IKDC score, procedure done by a senior or junior physician, and type of autologous graft (FSHG or BPBG). The propensity score was based on 19 potential confounding factors: age, gender, body mass index, smoking, high-level sports, time since inclusion, impairment of social activities, vitality, side involved, lesions of the medial meniscus, lesions of the lateral meniscus, procedure done by a senior or junior physician, type of autologous graft, constitutional laxity (yes/no), knee alignment, position of the patella, subluxation of the patella (yes/no), and baseline IKDC scores. The results obtained using the propensity-score method were similar to those of the multivariate logistic regression model: aOR = 1.09 [0.37–3.20], \(P = 0.873\).

No significant difference was found between the two groups when the IKDC dimensions were analysed separately.

In the control group, there was no significant difference between the FSHG and BPBG subgroups. In the CANS group, in contrast, a higher proportion of patients had an IKDC grade of A in the FSHG subgroup than in the BPBG subgroup (68.25% versus 39.13%, \(P = 0.013\)).

### Secondary evaluation criteria

#### Operating time, stay length, and learning curve
Mean operating time was 30 minutes longer in the CANS group than in the control group (\(P < 0.01\)) (Table 2). Experience affected the mean operating time: junior surgeons had mean operating times of 74 minutes in the control group and 102 minutes in the CANS group, whereas corresponding values for senior surgeons were 54 minutes and 77 minutes (\(P < 0.01\)).

Mean hospital stay length was four days in both groups. To assess the learning curve, we compared the mean operating time (in minutes) for the first 3 CANS patients in each study centre to the overall mean operating time of 87 minutes in the CANS group. The results varied widely, from +40 minutes to 0 minute.

#### Resumption of physical activities
Median rehabilitation therapy duration was 12 weeks (IQR, 8–20) in the control group and 12 weeks (IQR, 8–24) in the CANS group (\(P = 0.366\)).

No differences were reported between the two groups regarding the return to work, school, or sporting activities. Median time from study inclusion to the return to work or school was 79.5 days (IQR, 50–134) in the control group and 87 days (IQR, 54–126) in the CANS group (\(P = 0.602\)). Median time from inclusion to the return to sporting activities was 187.5 days (IQR, 136–242) in the control group and 197 days (IQR, 158–263) in the CANS group (\(P = 0.292\)). This variable was influenced neither by the type of sport (contact sport or other) nor by the level of sporting activity (high level or other).

#### Complications
Only 4 (1.5%) patients experienced immediate postoperative complications, two in each group. Adverse events occurred during the study period in 25 patients, 13 in the CANS group and 12 in the control group. Of the 6 patients who each experienced two adverse events, four were in the CANS group and 2 in the control group (Tables 3 and 4).

#### Other secondary evaluation criteria
The improvement in the subjective IKDC score was not significantly different between the two groups (\(P = 0.77\)) (Table 2).
Differential laxity at 150N measured by Telos radiography [7,8] was 1.38 ± 1.79 mm in the control group and

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<table>
<thead>
<tr>
<th>Table 2</th>
<th>Outcomes.</th>
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<tr>
<td></td>
<td>Control group</td>
</tr>
<tr>
<td>Success rate (IKDC A and B)</td>
<td>91/100: 91%</td>
</tr>
<tr>
<td>Radiographic laxity</td>
<td>1.38 ± 1.79 mm</td>
</tr>
<tr>
<td>Subjective IKDC</td>
<td>25.8 ± 18.7</td>
</tr>
<tr>
<td>Operating time, in minutes</td>
<td>74</td>
</tr>
<tr>
<td>Success rate (IKDC A and B)</td>
<td>94.3% for seniors versus 85.7% for juniors</td>
</tr>
<tr>
<td>Days to sports resumption</td>
<td>187.5 (136–242)</td>
</tr>
<tr>
<td>Femoral tunnel positioning (AB/AC)</td>
<td>68.6 ± 13.2</td>
</tr>
<tr>
<td>Tibial tunnel positioning (CTT/STD*100)</td>
<td>34.34 ± 11.7</td>
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</table>
1.77 ± 2.06 mm in the CANS group ($P = 0.384$). Stratification on type of graft failed to reveal any statistically significant differences. Differential laxity greater than 3 mm is considered clinically significant. The proportion of patients having differential laxity values lower than 3 mm was not significantly different between the two groups (72.4% in the control group versus 60.7% in the CANS group, $P = 0.35$).

Radiological tunnel position [9,10] was not significantly different between the two groups (Fig. 2). For the femoral tunnel, the AB/AC score was $68.6 ± 13.2$ in the control group and $71.2 ± 31.2$ in the CANS group ($P = 0.51$). For the tibial
tunnel, the CTT/STD*100 score was 34.34 ± 11.7 in the control group and 34.19 ± 9.7 in the CANS group (P = 0.93).

Discussion

The results of this study establish the large-scale feasibility of computer-assisted surgery for ACL reconstruction, as well as the excellent outcomes achieved using this technique. No significant difference versus conventional surgery was found regarding the primary evaluation criterion, i.e., the proportion of patients with an IKDC grade of A or B after 1 year.

Few studies have compared clinical outcomes after ACL reconstruction with versus without computer-assisted navigation. Plaweski et al. [4] used the ACL Logics system in 30 patients, who were compared to 30 patients managed by conventional surgery. The additional operating time was 26 minutes. After a mean follow-up of 2 years, differential laxity was lower in the navigation group: laxity was less than 2 mm in 96.7% of knees in this group compared to 83% in the conventional-surgery group. In addition, tibial tunnel positioning was significantly better in the navigation group. No statistically significant differences were found between the two groups for the functional scores or the resumption of sporting activities. Picard et al. [11] assessed tunnel placement with and without navigation in a prospective randomised trial. Two surgeons experienced in ACL reconstruction but inexperienced in computer-assisted navigation drilled tibial tunnels in 20 artificial knees. Accuracy in tunnel placement was significantly better with the navigation system. In a study of 8 junior surgeons, each of whom drilled 10 tunnels, Eichhorn [12] showed that navigation was accurate and highly reproducible. In addition, tunnel placement accuracy as assessed by radiography was better in a group of 300 reconstructions with navigation than in a group of 300 reconstructions without navigation [12]. Hiraoka et al. [13] compared conventional surgery to surgery with navigation in 16 patients. Tibial tunnel position was assessed using radiography and magnetic resonance imaging. The results showed better accuracy in the navigation group with decreased variability in tunnel position. In a prospective randomised trial, Enelle et al. [14] compared two groups of 20 patients managed with and without computer-assisted navigation and found no statistically significant differences in tunnel position or clinical outcomes. Burkart et al. [15] reported considerable variability among surgeons in tunnel placement using a navigation system.

Thus, few studies found a significant correlation between improved accuracy in tunnel positioning and improved clinical outcomes [16]. Several studies comparing tibial tunnel position with and without navigation demonstrated correct tunnel positioning by experienced surgeons [17–21], whereas few studies showed the opposite [4,22,23]. Navigation was associated with better femoral tunnel positioning in most studies [4,17,18,22,23].

Conclusion

When used for ACL reconstruction, a computer-assisted navigation system seems beneficial as a learning tool for junior surgeons and in difficult cases (tunnel positioning). Use of a navigation system increases the operating time but has no effect on the complication rate. Nevertheless, we found no evidence that the navigation system significantly improved the clinical outcomes. Thus, our results disprove our working hypothesis. Conceivably, given the young age of our patients, a longer-follow-up may be necessary to detect clinical benefits of improved anatomical reconstruction accuracy via the use of navigation.

Disclosure of interest

S. Plaweski is a consultant for Smith & Nephew and for Praxim Medivision.

None of the other authors has any conflicts of interest to declare.

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