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Restricted kinematic alignment may be associated with increased risk of aseptic loosening for posterior-stabilized TKA: a case–control study

Elliot Sappey-Marinier[1,2] · Jobe Shatrov[3,4,5] · Cécile Batailler[1,2] · Axel Schmidt[1] · Elvire Servien[1,6] · Emmanuel Marchetti[7] · Sébastien Lustig[1,2]

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Abstract

Purpose The purpose of the study was to compare clinical and radiological results between kinematic alignment (KA) and mechanical alignment (MA) with a posterior-stabilized (PS) total knee arthroplasty (TKA) with a post-cam mechanism at a minimum follow-up of 3 years. The authors hypothesized a higher risk of aseptic loosening when performing KA using PS TKA.

Methods A retrospective monocentric single surgeon case control study was performed comparing 100 matched patients who had TKA performed using a MA philosophy to 50 patients receiving TKA with a KA technique between January 2016 and October 2017. All patients had the same knee prosthesis (GMK primary posterior-stabilized, Medacta®, Switzerland). Patient specific cutting blocks were used in both groups and a restricted KA (rKA) was aimed in the KA group. A hybrid cementation technique was performed. The new Knee Society Score (KSS) and radiological assessment were collected preoperatively and at the final follow-up. Comparisons between groups were done with the *T* test or Fisher exact test. Global survival curves were estimated with Kaplan–Meier model. Significance was set at $p < 0.05$.

Results Mean follow-up was 42.9 months ± 3.6 (range 37.6–46.7) and 53.3 months ± 4.1 (range 45.5–59.8) for rKA and MA groups. Postoperatively, no significant differences were found for clinical scores between both groups. Radiological assessment found similar postoperative Hip–Knee–Ankle angle for rKA and MA groups (178° versus 179° respectively, NS). At last follow-up, a significant higher survivorship was found for the MA group compared to the rKA group (97 versus 84%; $p < 0.001$) for aseptic loosening revision as the endpoint.

Conclusion An increased risk of tibial implant loosening was found with rKA compared to MA using a posterior-stabilized TKA with a post-cam system at short-term follow-up. Caution should be taken when choosing the TKA design while performing rKA.

Level of evidence Retrospective case–control study, Level IV.

Keywords Tibial loosening · Restricted kinematic alignment · Mechanical alignment · Posterior-stabilized · Knee arthroplasty · Knee replacement

Introduction

Total Knee Arthroplasty (TKA) is considered the gold standard treatment for severe knee osteoarthritis [11]. For the last 4 decades, mechanical alignment (MA) has been the most common and widely seen as the gold standard [6]. Despite MA having reliable long-term implant survival and good to excellent patient reported outcomes in most of the population [6], nearly 20% of patients remain dissatisfied after TKA [9, 25]. Many authors have suggested that this dissatisfaction rate may be at least partially as a result of the systematic approach of MA [28, 30] as wide distribution of knee coronal alignment in osteoarthritic [32] and non-osteoarthritic [5] populations have been observed. Subsequently, alternative alignment philosophies [22, 29] have been developed including kinematic alignment (KA), which aims to reproduce constitutional knee alignment based on bony landmarks [17]. Venditolli et al. proposed a restricted kinematic alignment (rKA) philosophy to avoid excessive coronal deviation in TKA [2, 8].

✉ Elliot Sappey-Marinier
esappey@gmail.com; elliot.sappey-marinier@chu-lyon.fr

Extended author information available on the last page of the article

The KA philosophy reduces the need for ligament releases and achieves soft tissue balancing through bony cuts [7, 23]. Advocates of KA offer the rationale that this will improve clinical results in terms of pain and function compared to a MA technique [12, 13, 16]. Recent systematic reviews suggest that MA and KA in TKA achieved similar functional and radiological results [21, 33] and that KA may be an alternative alignment philosophy to MA in TKA. However, most studies included in these systematic reviews compared cruciate retaining (CR) TKA implants. It is unclear if these results apply to posterior-stabilized (PS) TKA implants with a post-cam mechanism.

The aim of this study was to compare clinical and radiological results between restricted kinematic and mechanical alignment using a PS TKA with a post-cam. The authors' hypothesis was that an increased risk of tibial implant loosening will be observed in the rKA group because of shearing stress of the plot on the post-cam especially when the tibial implant is put either in varus or valgus.

Materials and methods

All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study received institutional review board approval (number 2019-A02567-49), and all participants gave valid consent to participate.

Patients

A monocentric single surgeon (EM) retrospective analysis of consecutive patients who underwent primary TKA between January 2016 and October 2017 was performed. All PS TKA, performed with either a mechanical or restricted kinematic alignment philosophy, were included with a minimum follow-up of 3 years. Exclusion criteria were all TKA performed with another type of implant, patients not consenting to data collection or revisions TKA.

Demographics

Patient demographics are summarized in Table 1. One hundred and fifty patients were eligible for review. There were 100 patients in the mechanical alignment group and 50 patients in the KA group. Mechanical alignment was performed from January 2016 to March 2017 and KA was done from March to October 2017. Of the participants, 92 were females and 58 males. The female:male ratio was 58/42 for the MA group and 34/16 for the rKA group. There was no significant difference between patients for age, BMI or pre-operative range-of-motion. The MA group had a lower mean pre-operative patella tilt (0.3° vs 1.4°) compared to the rKA group and the mean KSS functional score was higher in the rKA group (45.7 vs 39.5) compared to the MA group (NS). However, neither of these differences reached statistical significance.

Table 1 Comparison of patient demographics by group at surgery

	Mechanical alignment group ($n = 100$)[a]	Kinematic alignment group ($n = 50$)[a]	*p* value
Age at surgery (year)	70 ± 8.5 [49–86]	68.2 ± 8.9 [53–85]	NS
Sex (female)	58/100 (58%)	34/50 (68%)	NS
BMI	29.7 ± 5.2 [17.9–46.7]	29.4 ± 5.5 [19.1–41.4]	NS
Preoperative flexion ROM (°)	114.9 ± 9.3 [90–130]	115 ± 10.0 [80–130]	NS
Preoperative mFTA (°)	176.3 ± 7.7 [158–193]	176.0 ± 6.3 [165–195]	NS
Preoperative FMA (°)	90.5 ± 3.8 [79–98]	91.3 ± 2.4 [86–96]	NS
Preoperative TMA (°)	87.3 ± 3.7 [77–95]	87 ± 3.0 [82–96]	NS
Preoperative tibial slope (°)	86.1 ± 1.4 [83–89]	86 ± 1.7 [83–90]	NS
Preoperative patellar tilt (°)	0.3 ± 3.1 [− 10–10]	1.4 ± 3.2 [− 10–10]	NS
Preoperative new KSS score	122.1 ± 24.5 [87–167]	122.1 ± 11.7 [12–69]	NS
Patient expectations	13.4 ± 2.6 [3–15]	13.9 ± 1.9 [9–15]	NS
Satisfaction	17.9 ± 7.4 [4–34]	17.1 ± 6.0 [10–34]	NS
Functional activities	39.5 ± 8.1 [27–69]	45.7 ± 17.3 [15–78]	NS

BMI body mass index (kg/m^2), *ROM* range-of-motion, *mFTA* mechanical femorotibial angle, *FMA* femoral mechanical angle, *TMA* tibial mechanical angle, *KSS* Knee Society Score, *NS* not significant

[a]Data are presented as mean ± standard deviation [minimum–maximum] or number (proportion)

Surgery

All patients had a medial sub-vastus approach performed for exposure without a tourniquet. In both groups, patient specific cutting blocks were used. For the MA group, femoral and tibial cuts were performed to place implants perpendicular to the mechanical axis of the bone. For the rKA group, a restricted KA philosophy was planned according to a technique that has previously been described by Venditolli [8]. The algorithm involves modifications of bone cuts within a "safe range" defined by criteria: independent femoral and tibial cuts must be within ± 5 of the mechanical axis and the HKA angle must fall within ± 3 of neutral. The same knee prosthesis was implanted for all patients (GMK Primary posterior-stabilized, Medacta®, Switzerland). Uniform hybrid cementation was performed in all cases; femoral component was uncemented, and tibial component was always cemented. To obtain an optimal cementation mantle without tourniquet, a Karcher high-pressure cleaning, followed by packing and drying was performed on the tibial cut surface. Palacos-RG high viscosity cement was used in all cases and was prepared in a mixing bowl. Application was first performed on the tibial surface using a blunt instrument to pressurize the cement into the interstices, and was also applied to the bone-implant interface of the prosthesis prior to implantation and impaction. Patella was selectively resurfaced according to the degree of patellar osteoarthritis found at the time of surgery.

Clinical and radiological assessment

For both groups, clinical evaluation scores were collected preoperatively and at the last follow-up during December 2020 using the new Knee Society Score (KSS) [34]. Radiological analysis (standard antero-posterior and lateral knee radiographs, full-length bilateral standing radiograph and patellar axial view radiograph) were performed preoperatively and at the last follow-up to assess the mechanical femorotibial angle (mFTA), the femoral and tibial mechanical angles measured medially (FMA and TMA, respectively), tibial slope, patellar tilt, incidence of radiolucent lines greater than 2 mm and implant loosening.

The complication rate was evaluated at the last follow-up, including all reintervention procedures (component exchange, debridement and irrigation, mobilization under anaesthesia and arthrolysis).

Statistical analysis

Statistical analysis was performed using XLSTAT software. Baseline descriptive data analysis using means, standard deviations and ranges was performed on each group. *T* test for independent samples were performed to compare group differences. Categorical variables were compared using a Fisher exact test. Survival analysis was conducted with reintervention as the endpoint. Global survival curves were estimated with Kaplan–Meier model and the comparison of survivorship between the different initial etiologies was estimated with log-rank. Significance was set at $p < 0.05$.

A post hoc analysis was performed with an odds ratio at 9.2, proportion of controls exposed at 0.02, a power at 0.8 and an alpha risk at 0.05. A minimum sample size of 46 cases and 92 controls was necessary for this study with a one case for two controls.

Results

Clinical outcomes

Mean follow-up was 42.9 months ± 3.6 (range 37.6–46.7) and 53.3 months ± 4.1 (range 45.5–59.8) for rKA and MA groups. In both groups, postoperative KSS scores were significantly improved compared to pre-operative scores. No significant differences were observed between both groups for clinical scores. All clinical results are reported in Table 2.

Table 2 Clinical assessments (including clinical scores and maximum knee flexion) at the last follow-up

	Mechanical alignment group	Kinematic alignment group	*p* value
Follow-up[a] (months)	53.3 ± 4.1 [45.5–61.1]	42.9 ± 3.6 [37.6–46.7]	< 0.001
Clinical assessment			
New KSS[a]	179.6 ± 19.6 [93–221]	173.2 ± 19.6 [121–206]	NS
Gain KSS[a]	57.5 ± 29.8 [− 27–122]	52 ± 30.4 [− 23–130]	NS
Patient expectation[a]	13.0 ± 2.1 [4–15]	11.5 ± 3.4 [3–15]	NS
Satisfaction[a]	30.7 ± 6.5 [12–40]	30.6 ± 7.4 [8–40]	NS
Functional activities[a]	63.1 ± 11.0 [26–85]	62.1 ± 12.5 [24–85]	NS
Maximum knee flexion[a] (°)	119.6 ± 9.0 [90–135]	121.3 ± 11.2 [95–140]	NS

NS not significant

[a]The values are given as mean and SD, with the range in parentheses

Radiological outcomes

There was no significant difference in mean mFTA between the two groups postoperatively (NS). Significant differences were found for FMA, TMA and tibial slope between both groups postoperatively (respectively, $p=0.002$, $p=0.03$ and $p<0.001$). In the rKA group, femoral components were slightly more in valgus (91.3 ± 2.4 versus 89.8 ± 1.3), tibial components were slightly more in varus (88.6 ± 2.6 versus 89.5 ± 0.9) and tibial slope was slightly increased (86.6 ± 1.4 versus 88.6 ± 1.1). Two outliers were > 5° proximal tibia varus and eight outliers were > 3° HKA varus. Anteroposterior radiographs revealed a significantly increased risk of tibial radiolucent lines in the rKA group (9 cases—30%) compared to the MA group (15 cases—30%); OR = 0.21, 95%CI [0.07; 0.56]; $p<0.001$). All radiological results are reported in Table 3. Comparisons of all radiological parameters for both groups were performed for TKA with and without loosening and are reported in Table 4.

Complications and revision

In the MA group, there were four complications during the follow-up period. One patient developed an early infection 2 months postoperatively and a complete revision with component exchange was performed. Another patient developed postoperative stiffness and underwent arthroscopic arthrolysis at 4 months postoperatively. Two other patients were revised because of aseptic tibial loosening at 38.4 and 45.1 months.

In the rKA group, all revisions (8 patients (16%)) for aseptic tibial loosening were performed between 11.9 and 25.5 months. Also, one patient presented tibial loosening and was advised to undergo revision surgery, but refused it.

For all septic and aseptic revisions, a Condylar Constrained Knee prosthesis was implanted.

At 50 months follow-up, the overall implant survivorship was significantly higher for the MA group compared to the rKA group (97 versus 84%; $p=0.002$) (Fig. 1). When considering aseptic loosening revision as the endpoint, a significantly higher survivorship was found for the MA group

Table 3 Radiological assessment at the last follow-up

	Mechanical alignment group	Kinematic alignment group	*p* value
Patellar tilt[a]	0.7 ± 3.5 [− 10 to 10]	0.8 ± 3.4 [− 10 to 5]	NS
mFT angle[a]	179.3 ± 2.7 [171–186]	178.8 ± 3.8 [173–188]	NS
Femoral mechanical angle[a]	89.8 ± 1.3 [88–92]	91.3 ± 2.4 [86–96]	0.002
Tibial mechanical angle[a]	89.5 ± 0.9 [88–92]	88.6 ± 2.6 [82–94]	0.03
Tibial slope[a]	88.6 ± 1.1 [86–91]	86.6 ± 1.4 [84–90]	< 0.001
Progressive radiolucent lines	9 (9%)	15 (30%)	< 0.001

NS not significant

[a]The values are given as mean and SD, with the range in parentheses

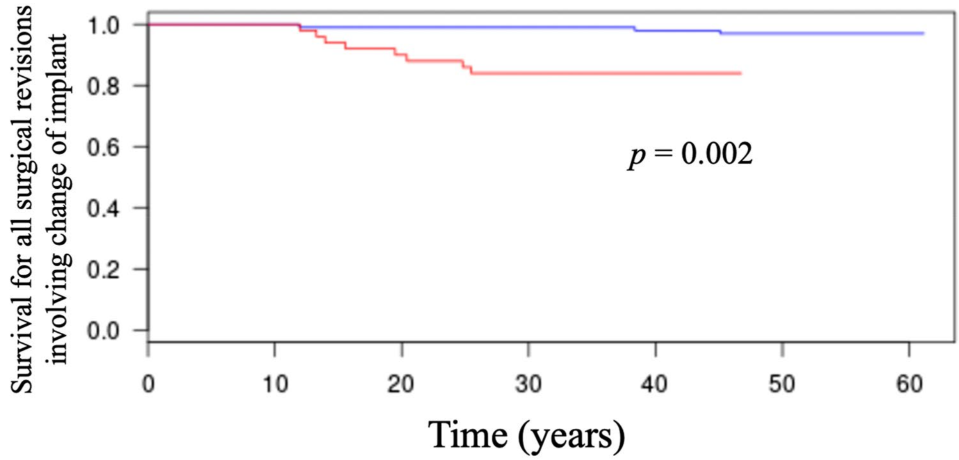
Table 4 Comparisons of tibial alignment between mechanical and kinematic groups for TKA with and without loosening

	Mechanical alignment group		*p* value
	Without loosening (*n* = 98)	With loosening (*n* = 2)	
mFT angle[a]	179.3 ± 2.7 [171–186]	180 ± 0 [180–180]	NS
Femoral mechanical angle[a]	89.8 ± 1.3 [88–92]	90 ± 0 [90–90]	NS
Tibial mechanical angle[a]	89.5 ± 0.9 [88–92]	89.5 ± 0.7 [89–90]	1
Tibial slope[a]	88.6 ± 1.1 [86–91]	87.5 ± 0.7 [87–88]	NS
	Kinematic alignment group		
	Without loosening (*n* = 42)	With loosening (*n* = 8)	
mFT angle[a]	178.8 ± 3.8 [173–188]	177.4 ± 2.3 [175–181]	NS
Femoral mechanical angle[a]	91.3 ± 2.4 [86–96]	91 ± 1.3 [89–93]	NS
Tibial mechanical angle[a]	88.6 ± 2.6 [82–94]	87.8 ± 1.5 [86–90]	NS
Tibial slope[a]	86.6 ± 1.4 [84–90]	86.8 ± 1.0 [85–88]	NS

mFT mechanical femorotibial, *NS* not significant

[a]The values are given as mean and SD, with the range in parentheses

Fig. 1 Survival for all surgical revisions involving complete change of implant for MA (blue) and rKA (red) groups



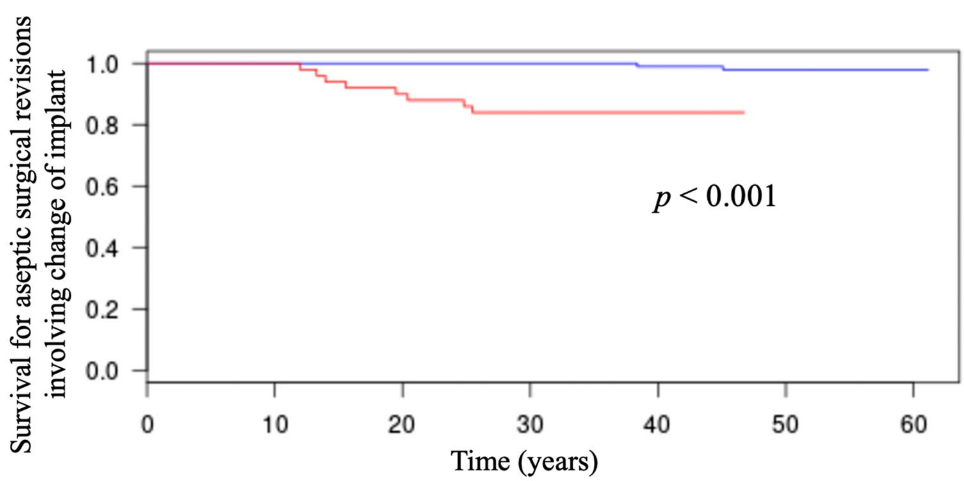
compared to the rKA group (98 versus 84%; OR = 9.2, 95% CI [1.7; 92.4]; $p < 0.001$) (Fig. 2).

Discussion

The most important finding of this case–control study is that an increased risk of aseptic tibial implant loosening was observed with rKA compared to MA using a posterior-stabilized TKA.

Limited data are available regarding survivorship of the GMK PS implant with hybrid fixation. The Australian National Joint Registry 2020 report recorded 23 revisions out of 643 TKA's performed at 5-year follow-up using the GMK primary implant with hybrid fixation [3]. This represents a 4.1% cumulative revision rate. The number of PS versus CR constrained implants was not available in the report and this, along with a difference in reporting time frame may explain the differences between the present study and data reported in the Australian Registry. The authors of the present study believe the increased tibial loosening seen in the rKA group is possibly due to implant design. When the tibial component is placed either in varus or valgus, an excessive shearing stress may be applied on the post-cam interface directly linked to the tibial implant leading increased sheer forces and potentially early aseptic loosening even with a cemented tibial component. Even if no significant difference was found for mFTA between both groups, significant differences were found for FMA, TMA and tibial slope which could be a plausible reason of tibial loosening. Supporting this theory is that many studies showed increased failure rates with postoperative alignment in the outlier category (beyond 0° ± 3) compared to neutral alignment when using posterior-stabilized TKA [15, 36]. Countering this argument are several studies [1, 37] that did not find significant difference in implant durability between the neutral alignment and outlier alignment group at long-term follow-up. Moreover, Nedopil et al. [26] reported higher incidence of tibial component failure when tibial slope was superior to 5° while using a KA philosophy. The authors of the present study did not consider tibial component failure due to loosening to be associated with any significant differences in tibial

Fig. 2 Survival for aseptic surgical revisions involving complete change of implant for MA (blue) and rKA (red) groups



alignment, although it should be noted that baseplates with loosening tended to have slightly more varus femorotibial angles and tibial mechanical angles. Also in the present study, it should be noted that some patients had tibial component placement much more in varus without loosening. Maybe with a longer follow-up these patients would also have tibial loosening.

Restricted kinematic alignment is increasingly being accepted as a surgical technique for TKA as the body of evidence supporting its use grows. Proponents of rKA argue the restoration of the tibio-femoral joint line back to its pre-arthritic position maintains the native soft tissue anatomy, preserving normal joint kinematics and ultimately an improvement in patient outcomes. Two randomized controlled trials involving CR implants reported improved short-term clinical results in favour of rKA [10, 12]. Whilst the reason for this observation is not fully understood, several studies have shown a reduction in the need for soft tissue releases with a rKA approach compared to MA, potentially explaining decreased postoperative pain [23, 24]. Another possible explanation for improvement in outcomes is tibio-femoral balancing, with a number of studies reporting less gap imbalance and a more natural gait with KA [7, 27]. Recent systematic reviews and meta-analyses have shown that KA achieves similar clinical and radiological similar to those of MA without increasing the complication rate [21, 31, 33].

Despite the growing enthusiasm in KA, concerns remain about longevity of implant survival. Indeed, there still is a concern that varus alignment of the tibial component may result in early implant loosening [14, 19]. However, studies of short- and mid-term follow-up have not shown an increased risk of implant loosening between KA and MA groups [21, 31, 33]. Furthermore, Howell et al. [18] in a long-term follow-up study reported no significant difference in complication rate in KA compared to MA TKAs at 10 year follow-up. These results differ from the present study where a significant increased risk of aseptic tibial implant loosening was observed in the rKA group. It is important to point out that in a vast majority of studies comparing implant survivorship between KA or rKA and MA alignment philosophy thus far have been with the use of CR TKA design [20]. The authors of the present study are only aware of two studies that have reported survivorship with the use of a PS TKA implants and a rKA philosophy, and in both cases there was short-term follow-up [23, 27], with the principal outcome measured not including implant survival.

This study has several limitations. Being retrospective, it constitutes the first major limitation. Second, a hybrid cementation was performed which could lead to potentially worse radiological results. However, recent studies found similar results between hybrid and full cementation TKA at long-term follow-up [4, 35]. Furthermore, all tibial components were cemented, and loosening was always observed on the tibial component in the present study. Third, follow-up was short- to mid-term and not identical for both groups due to this being a consecutive series, therefore, MA group follow-up was longer.

This study is clinically relevant since it serves as a cautionary note to surgeons performing rKA TKA, with prosthetic design potentially impacting on survival outcomes using this technique.

Conclusion

An increased risk of tibial implant loosening was found with rKA compared to MA using a posterior-stabilized TKA with a post-cam system at short-term follow-up. Caution should be exercised when choosing the TKA design whilst performing rKA.

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Declarations

Conflict of interest Prof. Sébastien Lustig has performed consultancy work for Medacta, Heraeus, Corin, Amplitude, Groupe Lépine, Depuy Synthes, Smith & Nephew, Stryker. Prof. Sébastien Lustig receives institutional research support from Corin and Amplitude. Prof. Sébastien Lustig is a board member of KSSTA, Maitrise Orthopédique and JBJS american. Dr Emmanuel Marchetti has perfomed consultancy work for Medacta and receives royalties from Medacta. The other authors declare that they have no conflicts of interest.

Ethical approval All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study received institutional review board approval (number 2019-A02567-49), and all participants gave valid consent to participate.

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Authors and Affiliations

Elliot Sappey-Marinier[1,2] · Jobe Shatrov[3,4,5] · Cécile Batailler[1,2] · Axel Schmidt[1] · Elvire Servien[1,6] · Emmanuel Marchetti[7] · Sébastien Lustig[1,2]

Jobe Shatrov
jobeshatrov1@gmail.com

Cécile Batailler
cecile.batailler@chu-lyon.fr

Axel Schmidt
axel.schmidt@chu-lyon.fr

Elvire Servien
elvire.servien@chu-lyon.fr

Emmanuel Marchetti
emmanuelmarchetti@yahoo.fr

Sébastien Lustig
sebastien.lustig@chu-lyon.fr

1 Orthopaedics Surgery and Sports Medicine Department, FIFA Medical Center of Excellence, Croix-Rousse Hospital, Lyon University Hospital, 103 Grande Rue de la Croix-Rousse, 69004 Lyon, France

2 Univ Lyon, Claude Bernard Lyon 1 University, IFSTTAR, LBMC UMR_T9406, F69622 Lyon, France

3 Sydney Orthopaedic Research Institute, Chatswood, Sydney, Australia

4 University of Notre Dame Australia, Sydney, Australia

5 Hornsby and Ku-Ring Hospital, Sydney, Australia

6 LIBM – EA 7424, Interuniversity Laboratory of Biology of Mobility, Claude Bernard Lyon 1 University, Lyon, France

7 Centre Orthopédique Fleming, 30 Avenue Alexandre Fleming, 38300 Bourgoin-Jallieu, France