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Isolated ACL reconstruction
vs combined with Lateral
Extraarticular Procedures
in patients 25 or younger: A
Systematic-Review with
meta-analysis.

U. PORTO



**FACULDADE DE MEDICINA
UNIVERSIDADE DO PORTO**

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Eu, António Frederico dos Santos Frias Correia, abaixo assinado, nº mecanográfico 201807455, estudante do 6º ano do Ciclo de Estudos Integrado em Medicina, na Faculdade de Medicina da Universidade do Porto, declaro ter actuado com absoluta integridade na elaboração do meu trabalho de Dissertação ou Monografia.

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Faculdade de Medicina da Universidade do Porto, 20/03/2024

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DESIGNAÇÃO DA ÁREA DO PROJECTO

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Isolated ACL reconstruction vs combined with Lateral Extraarticular Procedures in patients 25 or younger: A Systematic-Review with meta-analysis.

ORIENTADOR

Professor Doutor Manuel António Pereira Gutierres

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**UC Dissertação - DECLARAÇÃO DE TRANSPARÊNCIA
RELATIVAMENTE À UTILIZAÇÃO DE FERRAMENTAS DE CHATBOT
GENERATIVO BASEADAS EM LARGE LANGUAGE MODELS**

Eu, António Frederico dos Santos Frias Correia, abaixo assinado, nº mecanográfico 201807455, estudante do 6º ano do Ciclo de Estudos Integrado em Medicina, na Faculdade de Medicina da Universidade do Porto, declaro que:

- ☒ Não procedi à utilização de ferramentas de *chatbox* generativo baseadas em *large language models* para nenhuma das tarefas no contexto do meu trabalho de Dissertação ou Monografia
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Faculdade de Medicina da Universidade do Porto, 20/03/2024

Assinatura conforme cartão de identificação: António Frederico dos Santos Frias Correia

Isolated ACL reconstruction vs combined with Lateral Extraarticular Procedures in patients 25 or younger: A Systematic-Review with meta-analysis.

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Declarations

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Abstract:

Introduction: ACL ruptures are extremely prevalent worldwide. Despite the commonness of this injury, isolated ACL Reconstruction (ACLR) results remain insufficient, with young patients reporting high rates of graft failure. Recent studies reported some improvements when a Lateral Extraarticular Procedure (LEAP) was performed concomitantly with ACLR in a general population. This study aims to assess if the addition of a LEAP to ACLR leads to better clinical outcomes in patients 25 or younger.

Materials and methods: This study was performed according to the PRISMA guidelines. The literature search, data extraction, and quality assessment of the studies were conducted by 2 independent reviewers using PubMed, Scopus and Web of Science. We included studies comparing isolated ACLR to ACLR with LEAPs in patients 25 or younger that reported on graft failure rate or patient-reported outcomes (PROs).

Results: Six articles and 1280 patients were included. Our meta-analysis showed that the addition of a LEAP significantly reduced graft failure rate ($RR = 0,31$; 95% C.I. $[0,19; 0,53]$) and lead to higher rate of return to sports at the same level ($RR = 1.2943$; 95% C.I. $[1,2051; 1.3901]$). One of the studies also reported better pivot-shift test results when a LEAP was added. On the contrary, one study reported worse PROs in the first months after surgery with the addition of a LEAP. No statistically significant differences were found in PROs at final follow-up or any remaining outcomes.

Conclusion: Adding a LEAP to ACLR in patients 25 or younger appears to lower graft failure rate and improve the rate of return to the same level of sports. PROs appear to be worse in the initial months when a LEAP is added but eventually evolve to be similar or possibly even better. More studies are needed to solidify the findings of this review.

Study Design: Systematic Review; Level of evidence, 3.

Keywords: ACL Reconstruction; Lateral Extraarticular Procedures; anterolateral ligament reconstruction; lateral extraarticular tenodesis; graft failure; young patients

Introduction:

Anterior Cruciate Ligament (ACL) injuries are one of the most prevalent injuries worldwide[1] and its incidence is rising at an alarming rate in younger and more active patients[2]. The evolution in the treatment of this injury has led to various techniques being implemented with, recently, a bigger focus being given to intraarticular reconstruction using various grafts and techniques[3]. However, despite the advancements in intraarticular reconstruction there is still room for improvement in addressing rotatory instability and the high risk of graft rupture. The results from isolated intraarticular ACL reconstruction (ACLR) are particularly underwhelming in younger populations[4-6].

The anterolateral ligament (ALL), recently rediscovered by Claes et al.[7] (even though a “pearly, resistant, fibrous band” at the anterolateral aspect of the human knee had been previously described by Segond in 1879[8]), appears to have a role in rotatory stability of the knee[9], with injury to this ligament leading to worse clinical results after isolated ACLR[10, 11]. For this reason, there has been an increased interest in combining ACLR with a Lateral Extraarticular Procedure (LEAP), either a lateral extraarticular tenodesis (LET) or an anterolateral ligament reconstruction (ALLR) with both increasing knee stability at time zero after surgery and having a potential protective effect on ACL graft in biomechanical studies[12]. These improvements appear to be translating into clinical settings with recent systematic reviews demonstrating less graft failures and lower knee residual laxity with the addition of either of these procedures[13-15].

However, it appears that not all patients benefit from performing a LEAP and with potential overconstraint of the knee[16] and other adverse effects [17-21], it becomes essential to define clear indications for these procedures. Vundelinckx et al.[22] and Sonnery-Cottet et al.[23] recently attempted to identify the patients that would benefit the most from the addition of a LEAP and both considered being ≤ 25 as potential criteria for these procedures. The aim of this review is to report on clinical outcomes of adding either a LET or an ALLR in this population to answer the question: Should we add LEAPs to ACLR in patients 25 or younger?

Materials and methods:

Study selection and search strategy

The systematic review was performed according to the PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[24]. A comprehensive search was conducted across multiple databases (PubMed, Scopus and Web of Science) from the date of database inception through to February 14 of 2024. The Medical Subject Headings and Boolean operator terms used for the search were [(“Anterior cruciate ligament reconstruction” OR “ACL reconstruction”) AND (“Extraarticular” OR “Anterolateral ligament” OR “Lateral Extraarticular Tenodesis” OR “Macintosh” OR “Lemaire” OR “Ellison”)].

Eligibility criteria

We included studies that (1) compared isolated ACLR to ACLR with a LEAP (LET or ALLR) (randomized controlled trials, prospective or retrospective cohort studies); (2) the population consisted of people aged 25 or younger; (3) reported on at least one of the following outcomes: Lysholm Knee Scoring Scale (LKSS); International Knee Documentation Committee Subjective Knee Form (IKDC-SKF); Knee injury and Osteoarthritis Outcome Score (KOOS), Tegner Activity Scale (TAS) or Graft failure; (4) had a minimum follow-up period of 24 months and (5) were written in English, Spanish or Portuguese language.

The exclusion criteria were as follows: (1) studies not performed on humans; (2) cadaveric studies; (3) studies about secondary ACLR, ACL revision surgeries or the addition of a LEAP following an initial isolated ACLR; (4) studies that reported on the simultaneous reconstruction of the ACL and the posterior cruciate ligament or the lateral collateral ligament and (5) studies that applied different intraarticular procedures in the isolated ACLR group when compared to the ACLR with LEAP expecting different outcomes (for instance a study comparing double bundle ACLR alone with single bundle ACLR plus LET would be excluded however studies comparing isolated hamstring graft intraarticular ACLR with a modified Macintosh procedure that combined both the intraarticular and extraarticular procedures using the iliotibial band were still included).

Following the exclusion of duplicated studies, two authors (AFC and OBS) reviewed the title and abstract of each article to exclude those that did not meet the requirements. Afterwards, the full texts of the remaining articles were reviewed. Any conflicts on article inclusion were resolved by discussion between the two.

Data extraction

The relevant data from eligible studies was extracted by two independent reviewers (AFC and JPM). The extracted data included study demographic data (study design, surgical techniques, inclusion and exclusion criteria, criteria used to perform the LEAP, sex, mean age, number of participants in each group and follow-up time) and the following outcomes: (1) graft failure rate; (2) patient reported outcomes (PROs) at 3, 6, 12 months and at final follow-up including IKDC-SKF, KOOS, LKKS and TAS; (3) return to sports rate, time to return to sports and rate of return to sports at the same level; (4) non-graft related reoperations rate, rate of reoperations due to meniscal injury and rate of reoperations due to causes other than graft failure and meniscal injury in the previously operated knee; (5) pivot-shift test results and (6) side-to-side laxity

differences according to the KT-1000 arthrometer. The patients were divided in control group when an isolated ACLR was performed and experimental group when a LEAP was performed concomitantly to the ACLR. Any discrepancies in data extracted were resolved by discussion between the two reviewers.

Quality assessment

The risk-of-bias of the included studies was independently assessed by 2 examiners (AFC and OBS) using the ROB-2: A revised Cochrane risk-of-bias tool for randomized trials[25] and ROBINS-I: Risk Of Bias In Non-randomised Studies - of Interventions[26]. If there was a disagreement, the two examiners came to a decision by discussion.

Data synthesis and analysis

A meta-analysis was performed when two or more sets of the same data were reported in the outcomes. Data analysis was performed using the R package meta. The risk ratio (RR) and its corresponding 95% C.I. were calculated for dichotomous data. For continuous variables assessed in the same way between studies, we calculated the mean difference (MD) and 95% C.I.. Heterogeneity was assessed by the I^2 statistic and an I^2 value >50% was considered to indicate significant heterogeneity. Since we allowed for different population characteristics to be included and surgical techniques to be performed, possibly leading to substantial between-studies variance, we opted to use the random effects model for the meta-analysis. No sensitivity analysis or subgroup analysis was performed due to lack of studies reporting each outcome and, for the same reason, publication bias was not assessed according to funnel-plots. When an outcome was considered relevant for this review but only one study reported on it or it was not possible to perform meta-analysis, the results were compiled in tables.

Results

Literature Search

The initial literature search resulted in 3357 total studies. After duplicates were removed 1706 articles were screened for their title and abstract with further removal of 1630 articles. The remaining 76 articles were read in their entirety and 6 of these studies were included in this review. The detailed results of the search for relevant literature based on the strategy described above can be found in Figure 1.

Study Characteristics

A total of six articles[27-32] were included: 1 randomized controlled trial[27] and 5 cohort studies[28-32]. A total of 1280 patients were included in this systematic review and meta-analysis with 632 patients in the control group (isolated ACLR) and 648 patients in the experimental group (ACLR with a LEAP). We found different criteria for eligibility of populations, different criteria for performing the LEAP and different surgical procedures in the included articles. – Table 1.

Study Quality Assessment

The quality assessment for the randomized controlled trial [27] was performed using the RoB-2 tool that revealed some concerns in the overall risk-of-bias - Table 2.

The quality of the remaining 5 non-randomized trial studies[28-32] was assessed by the ROBINS-I tool (Risk Of Bias In Non-randomized Studies – of Interventions) with all of the studies reporting an overall moderate risk-of-bias - Table 3.

Graft Rupture Rate

The graft rupture rate was analysed in all studies [27-32] including 633 patients in the experimental group and 619 patients in the control group. Analysis indicated no significant heterogeneity and the graft rupture rate was significantly lower in the experimental group compared to the control group (RR = 0,31; 95% C.I. [0,19; 0,53]; $I^2 = 0$). - Figure 2.

PROs at final follow-up.

IKDC-SKF was analysed in four studies[27, 28, 30, 31] including 560 patients in the experimental group and 514 patients in the control group. There were no significant differences between groups and no significant heterogeneity was detected (SMD: 0,04; 95% C.I. [-0,09; 0,17]; $I^2 = 0$) - Figure 3a

The KOOS score was analysed in three studies[27, 28, 31] including 560 patients in the experimental group and 514 patients in the control group. No significant heterogeneity and no significant differences between groups were found for the KOOS Pain, KOOS Symptoms, KOOS Activities of Daily Living, KOOS Sports and Recreation and KOOS Quality of Life. (KOOS Pain: SMD = -0,01; 95% C.I. [-0,17; 0,14], $I^2 = 0\%$; KOOS Symptoms: SMD = 0,03, 95% C.I. [-0,10; 0,17], $I^2 = 0\%$; KOOS Activities of daily living: SMD = 0,07, 95% C.I.[-0,39; 0,54], $I^2 = 44\%$; KOOS Sports and Recreation: SMD = 0,04; 95% C.I. [-0,08; 0,17], $I^2 = 0\%$; KOOS Quality of Life: SMD = -0,01; 95% C.I. [-0,18; 0,15], $I^2 = 0\%$) – Figure 3b, 3c, 3d, 3e, 3f.

The LKKS was analysed in two studies[30, 31] including 220 patients in the experimental group and 215 patients in the control group. No significant heterogeneity and no significant differences between groups were reported. (SMD = 0,00; 95% C.I. [-0,30; 0,30], $I^2 = 0$) - Figure 3g

The TAS was reported in three studies[28, 30, 31] including 291 patients in the experimental group and 249 patients in the control group. However, only one study reported the mean with the two others reporting the median. For this reason, we were not able to conduct a meta-analysis for this outcome, but the results showed statistically significant higher results in the experimental group for two studies - Table 4.

PROs at 3,6 and 12 months

Getgood et. al.[27] further reported on PROs at 3-, 6- and 12-months post-surgery in 269 patients in the experimental group and 265 patients in the control group. It reported on the IKDC-SKF score and KOOS scores with results showing statistical significance in several PROs favouring the control group. - Table 5.

Other complications

The non-graft related reoperation rate was analysed in four studies[28, 30-32] including 310 patients in the experimental group and 286 patients in the control group. In three studies[28, 30, 31] including 294 patients in the experimental group and 273 patients in the control group, it was possible to further analyse the reoperations due to meniscal injuries and the reoperations due to other causes in the previously operated knee (including arthrolysis, cyclops, hardware removal and infection). Analysis indicated no significant heterogeneity between groups and, despite the rate of non-graft related reoperation (RR = 0.7938; 95% C.I. [0.4858; 1.2973]; $I^2 = 0\%$) and reoperation due to meniscal lesions (RR = 0.5597; 95% C.I. [0.0841; 3.7259]; $I^2 = 25\%$) being lower and the rate of reoperations due to causes other than graft failure and meniscal injury in the previously operated knee (RR = 1.1361; 95% C.I. [0.3997; 3.2289]; $I^2 = 0\%$) being higher in the experimental group, the random effects model showed no statistically significant differences between groups. - Figure 4.

Sports related outcomes

The return to sports rate was analysed in all studies[27-32], including 645 patients in the experimental group and 607 patients in the control group; the time to return to sports was analysed in two studies [29, 31], including 118 patients in the experimental group and 113 patients in the control group and the rate of return to the same level of sports was analysed in another two studies[30, 31], including 220 patients in the experimental group and 215 patients in the control group. Analysis indicated no significant heterogeneity and no significant differences between groups in either the return to sports rate (RR = 1,00; 95% C.I. [0,95; 1,06]; $I^2 = 0\%$) or the time to return to sports (SMD = 0,09; 95% C.I. [-1,41; 1,59]; $I^2 = 0\%$). However, the return to the same level of sport was significantly higher in the experimental group (RR = 1.2943; 95% C.I. [1.2051; 1.3901]; $I^2 = 0\%$). - Figure 5.

Knee laxity

The pivot-shift was reported on the study by Monaco et. al.[28] in a total of 35 patients in the control group and 61 patients in the experimental with statistically significant lower rate of grade 3+ pivot-shift results and higher rate of grade 0 pivot-shift results in the experimental group – Table 6.

The side-to-side laxity differences assessed by the KT-1000 arthrometer were reported on two studies [28, 29]. A meta-analysis was performed with no statistically significant differences being founded despite the experimental group reporting a lower side-to-side laxity difference (SMD = -0.9376; 95% C.I. [-2.9066; 1.0314]). - Figure 6.

Discussion

The rate of graft failure remains a huge concern after ACLR with studies reporting graft failure rates as high as 14% in adults and 38% in adolescents[5] and being younger than 20 leading to three times higher risk of graft failure[6]. While a big part of this increased rate in younger people may be attributed to the higher levels of activity and the higher rate of return to strenuous sports[4, 33] other factors also seem to contribute with adolescent patients reporting poorer healing of the anterolateral ligament 1-year after isolated ACLR when compared to an adult population.[34]. Despite the somewhat still uncertain reasoning behind the rate of graft failure in the younger population, the fact is that it remains unacceptably high and with the significantly worse outcomes of revision ACLR when compared to primary ACLR[35, 36] it becomes essential to find ways to lower the graft failure in patients 25 or younger without worsening other clinical outcomes.

Biomechanical studies showed that the addition of a LEAP more reliably restores normal knee stability and kinematics[12] and several systematic reviews have since confirmed the potential benefits of LEAPs in a clinical setting, with the addition of these procedures resulting in a significant lower graft failure rate in a general population. Beckers et al.[15] included 10 studies and 1844 patients: OR 0.26, 95% CI [0.17; 0.41], $I^2 = 0\%$; Na et al.[13] reported on 14 studies and 2099 patients: OR 0.31, 95% CI, [0.20; 0.48]; $I^2 = 0\%$ and Lai et al.[14] reported on 12 studies and 1503 patients: RR 0.30, 95% CI [0.19; 0.4], $I^2 = 0$. Our meta-analysis reported statistically significant lower graft rupture rate in patients in the experimental group when compared to the control group showing that, similarly to the general population, the subpopulation of patients younger than 25 also appears to benefit from having a LEAP when it comes to graft failure.

The PROs that we included in our study had all been previously validated following ACLR[37]. The IKDC-SKF is a reliable and valid measure of symptoms, function, and sports activities for patients with a variety of knee problems[38]; the KOOS is a knee-specific instrument developed to assess the patients perception of their knee problems regarding Pain, Symptoms, Activities of Daily Living, Sports and Recreation Function and Quality of Life[39]; the LKKS is a scoring system for examining a patient's knee-specific symptoms including mechanical locking, instability, pain, swelling, stair climbing, and squatting and the TAS is a patient-reported measure that describes the level of work- and sports-based activity in which a patient can engage[40]. For all the PROs we included in our study, our meta-analysis showed no statistically significant differences between the experimental and control group. However, for the TAS, 2 of the 3 studies we included in our review showed significant superiority favouring the experimental group. The results of PROs vary in other systematic reviews: For the IKDC-SKF, Beckers et al.[15] and Lai et al.[14] showed no statistically significant differences between groups but Na. et al.[13] showed a statistically significant superior score when a LEAP was performed with high heterogeneity being reported in the meta-analysis (MD: 2.65; 95% CI [0.91; 4.49]; $I^2=96\%$). The KOOS was only reported on the study by Lai et al.[14] for the subscale of Sports and Recreation and similarly to our meta-analysis reported no significant differences between groups. The LKKS was reported by Beckers et al.[15] and Na et al.[13] with both studies showing statistically significant superiority when a LEAP was performed but also reporting high heterogeneity according to the I^2 statistic (Beckers et al. [15]: MD 2.86; 95% CI [1.37; 4.36], $I^2 = 63\%$ and Na et al.[13]:

MD 3.02; 95% CI [1.31; 4.74]; $I^2=88\%$). Finally the TAS was reported by Na et al.[13] and Beckers et al. [15] and while Na et al. reported, similarly to 2 of our 3 studies, a significantly superior result when a LEAP was performed with high heterogeneity between studies (MD: 0.80; 95% CI [0.08; 1.52]; $I^2=94\%$), Beckers et al.[15], showed no statistically significant differences between the two groups. The study by Getgood et al.[27] further reported on PROs at 3,6 and 12 months post-surgery with the control group showing significantly better results in the: IKDC-SKF at 3 and 6 months, KOOS Pain at 3 and 6 months, KOOS symptoms at 3 and 6 months, KOOS ADL at 3 and 6 months, KOOS Recreation at 3 and 6 months and KOOS QOL at 3,6 and 12 months. By analysing the results of our study and further assessing other systematic reviews it appears that while the PROs eventually evolve to be not worse or even better with the addition of a LEAP to ACLR, in the initial months following the surgery these procedures lead to worse PROs with more pain and symptoms, less activity and worse quality of life.

The complications of adding LEAPs have previously been addressed with studies reporting higher rate of: cyclops[20], surgical site infection [21] and septic arthritis[19] when these procedures were added. Our meta-analysis showed a lower reoperation rate due to meniscal lesion and higher reoperation rate due to causes other than graft failure and meniscal lesions in the previously operated knee (including arthrolysis, cyclops, hardware removal and infections) in our experimental group. However, none of the differences reported were sufficient to translate into statistical significance. Our review indicates that while there might be an increased risk of some complications when a LEAP is performed, these procedures also appear to have a protective factor in secondary meniscal injuries after ACLR (possibly explained by the association between meniscal lesions and residual knee laxity[41])

Practicing sports can be an enormous concern for younger and more active patients [42] so it is important to assure that following the surgery patients are able to return to sport activities, to do so in the least amount of time possible and to return to the same level they were at before the injury. Our meta-analysis showed no statistically significant differences in return to sports rate and time to return to sports. These results are similar to those reported by Lai et al. and Beckers et al.[14, 15] that showed no significant differences between groups in the return to sports rate. However, studies have reported that despite the seemingly high return to sports, most athletes fail to achieve good results in their sport after isolated ACLR, with a big part not returning to their pre-injury level [43]. Our meta-analysis reported a higher return to sports at the same level in our experimental group, despite only 2 studies being included, suggesting that the addition of a LEAP could potentially lead to better results in the level of sports the patients return to.

The pivot shift is a test utilized for assessment of rotatory instability consisting of a manually subjective clinical test that simulates the injury mechanism. There is a lack of consensus among clinicians as to a standardized way to perform this test[44], however, since in the study by Monaco et al.[28] the pivot shift test was executed and graded by a single surgeon it did not lead to interobserver differences. In this study, at the final follow-up, the rate of grade 0 pivot-shift test was significantly higher and the rate of grade 3+ pivot-shift was significantly lower in our experimental group. These results are similar to those reported other systematic reviews where the pivot-shift test grade II and III occurred at a statistically significant higher rate in the isolated group when compared to the ACLR with LEAP (Beckers et al. [15]; OR = 0.42;

95% CI [0.26; 0.65]; $I^2 = 0\%$ and Lai et al. OR = 0.30; 95% CI [0.18; 0.49], $I^2 = 0\%$). Besides the clinical assessment of knee laxity through the pivot-shift test there are devices to analyse knee laxity more objectively. The KT-1000 knee arthrometer (KT-1000) is an instrument that measures anterior tibial motion relative to the femur, objectively assessing knee laxity[45]. Our meta-analysis showed that the addition of a LEAP leads to lower results in side-to-side laxity differences according to the KT-1000, however, no statistical significance was found between groups. Beckers et al. and Lai et al.[14, 15] reported significantly lower postoperative knee laxity with the addition of a LEAP despite high heterogeneity between studies (Becker et al.[15]: MD = -0.64, 95% [CI -1.20; -0.08], $I^2 = 94\%$ and Lai et al.[14]: MD = -0.55, 95% CI [-0.98; -0.12], $I^2 = 87\%$). Both the pivot-shift and the side-to-side laxity differences assessed residual laxity after ACLR and our review and further assessment of other studies indicates better results for these two outcomes when a LEAP is performed. A recent cohort study by Lindanger et al.[46] suggests that higher knee laxity at 6 months leads to higher graft failure rates and worse clinical outcomes at long-term follow-up (25 years), further implying the clinical importance a LEAP may have in long term outcomes.

Limitations

This study had several limitations affecting the strength of the conclusions that can be drawn from this analysis. Primarily, the scarcity of studies on the subject lead to only six studies being included with only one being a randomized controlled trial and the other five being cohort studies, therefore having the limitations inherent to these study designs. Additionally, our risk-of-bias analysis of the included studies indicated some reasons for concern for the randomized controlled trial and moderate overall risk-of-bias for the remaining cohort studies.

Furthermore, the patients included in the studies had factors other than age alone possibly affecting the results. This is particularly important since the study with more weight on our meta-analysis (the study by Getgood et al.[27]) only included patients with high knee laxity and a recent study by Eggeling et al. [47], despite its retrospective nature and small sample, suggested that adding a LEAP to revision ACLR in patients with low-grade anterior knee laxity did not influence PROs or graft failure rates. Also complicating our analysis were the inclusion of all surgical procedures with potential differences in outcomes with different graft types (patellar tendon autograft, hamstring autograft, allografts, or others); surgical techniques (such as double bundle and single bundle procedures) and LEAPs performed (LET or ALLR and different techniques for each of these procedures) not being analysed. Another limitation of the review were the differences in skeletal maturity between studies due to potential risk of growth arrest, limb-length discrepancies, and angular deformities when ACLR is performed on open physis [48]. In these cases, nonsurgical treatment or delayed reconstruction has been associated with worse outcomes, however questions remain on whether transphyseal; physeal-sparing or all-epiphyseal techniques are preferred for ACLR [48] and while the addition of a LEAP appears safe in these populations there are no reports on long term complications[49].

This review did not report on long term outcomes with only 24 months of follow-up being enough to be included in our study and therefore not reporting if the improvements caused by the addition of a LEAP are maintained following the initial years after the surgery. The lack of long-term studies also made it

impossible to analyse the rate of osteoarthritis, particularly important since addition of a LET appears to lead to overconstraint of the knee[16]. Other literature reporting on osteoarthritis shows no consensus with Devitt et al.[50] showing no increase in osteoarthritis with a LET but Castoldi et al.[51] finding that patients who underwent ACLR with LET had a greater rate of lateral compartment osteoarthritis compared with patients who underwent isolated ACLR.

By detailing these limitations, we are further reinforcing the need for future research to focus on randomized controlled trials in younger cohorts, with no other factors except for age being considered for the inclusion in the study. More randomized controlled trials in young cohorts should also focus on a longer follow-up term. If more studies further suggest that the addition of a LEAP leads to better clinical outcomes, then there needs to be a focus on randomized controlled trials comparing different surgical techniques and grafts to find the better intra and extraarticular ACLR in young patients for open and for closed physis.

Conclusion

This systematic review and meta-analysis showed lower graft failure rate and higher return to the same level of sport when a LEAP was performed. Despite our review suggesting worse PROs in the initial months when a LEAP is added, our meta-analysis showed no statistically significant differences in PROs at final follow-up with only TAS reporting significantly superior scores in 2 out of 3 studies with the addition of these procedures. Our review also suggests better pivot-shift test results with the addition of these procedures. These results are supported by other systematic reviews and studies performed on a general population and by limiting the population of this review to patients 25 years or younger, a population at high risk of graft failure, we further justify the inclusion of this subpopulation as possible criteria for the addition of a LEAP. More randomized controlled trials should focus on the addition of a LEAP in patients 25 or younger and longer follow-ups are needed in order to further solidify the conclusions of this study.

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Study (author and year)	Study design	Surgical techniques	Inclusion and exclusion criteria for the patients of the study	Criteria to perform a LEAP	Participants in each group	Age	Sex (M/F)	Follow up Time
Getgood (2020)	Randomized controlled trial	ACLR alone - single-bundle hamstring ACL reconstruction alone ACLR + LET - single-bundle hamstring ACL reconstruction combined with a modified Lemaire LET	Inclusion criteria: age between 14 and 25; ACL-deficient knee and thought to be at higher risk of reinjury based on the presence of 2 or more of the following factors: participation in competitive pivoting sports; presence of a grade 2 pivot shift or greater; generalized ligamentous laxity (Beighton score of 4 or greater) or genu recurvatum greater than 10°. Exclusion criteria: previous ACLR on either knee; multiligament injury; ligaments requiring surgical attention; a symptomatic articular cartilage defect requiring treatment other than debridement; greater than 3 of asymmetric varus; unable or unwilling to be followed up for 2 years postoperatively and skeletally immature.	randomized	ACLR alone - 312 ACLR + LET - 306	18.9 years (range, 14-25 years)	ACLR alone - 151/61 ACLR + LET - 151/55	2 years -14 lost withdrawn or lost to follow up in ACLR alone group and 15 withdrawn or lost to follow up in ACLR + LET group.
Laboudie (2022)	Cohort study	4HT - Quadruple hamstring tendon 4HT + ALL - Quadruple hamstring tendon + Anterolateral ligament reconstruction	Inclusion criteria: primary ACL reconstruction with an isolated 4HT (Group 1) or 4HT + ALL (Group 2); age < 20 years and athlete practicing a pivoting sport. Exclusion criteria: age > 20-years; absence of practice of a pivoting sport; prior knee surgery; multi-ligament injury; other graft; refusal to participate.	Based on ALL Expert group recommendations: pivot shift ≥ grade 2, hyperlaxity (knee recurvatum > 10°), high level athlete (competing at regional or national level), Second fracture (bony avulsion of the tibial ALL insertion on radiograph)	4HT - 101 4HT + ALL - 102	16.3 ± 2 years (range 11–20 years)	4HT – 57/44 4HT + ALL – 62/40	4.8 ± 0.9 years (range: 3.3–6.8) – 37 lost to follow up

Monaco (2022)	Cohort study	Isolated ACLR - Transphyseal quadruple hamstring tendon autograft ACL reconstruction alone ACLR + LET - Transphyseal quadruple hamstring tendon autograft ACL reconstruction alone + Arnold-Coker modification of the MacIntosh procedure	Inclusion criteria; ages 10-17 ACLR at Sant'Andrea University Hospital between January 1, 2013, and December 31, 2017. Exclusion Criteria: Tanner stage 1 and 2; ≥ 18 years; concomitant fractures (with the exception of Second fractures) and multiligamentous injuries that required surgery in addition to ACLR (patients with meniscal and cartilage lesions were included in the study)	Patients with 1 of the following additional risk factors for a graft rupture (pivot-shift grade 2 or 3, high level of sporting activity defined as TAS 7, participation in pivoting sports, and Second fractures) were offered LET in addition to ACLR.	isolated ACLR - 40 ACLR+ LET - 71	16.2 $\pm$ 1.4 years (range 13.0-17.6 years)	isolated ACLR - 25/15 ACLR+ LET - 44/27	43.86 $\pm$ 17.6 months (24-89) - 36.56 $\pm$ 15.6(24-89) in the isolated ACLR group and 47.96 $\pm$ 17.2 (24-89) in the ACLR+ LET group with 7 lost to follow up
Perelli (2022)	Cohort study	Group 1 - Autologous 4-strand hamstring graft anatomic ACL reconstruction alone Group 2 - Autologous 4-strand hamstring graft anatomic ACL reconstruction alone + modified Lemaire anterolateral tenodesis	Inclusion criteria: skeletally immature (maximum bone age of 16 years in boys and 14 years in girls); diagnosis of a primary ACL rupture; patients willing to return to sports activities after the rehabilitation process and patients who had undergone ACL reconstruction with an autologous hamstring graft. Exclusion criteria: a follow-up period <24 months after the index ACL reconstruction; a concomitant grade 2 or more tear of any other knee ligament (medial collateral ligament, lateral collateral ligament, posterior cruciate ligament); cartilage injuries requiring surgical treatment at the time of the ACL reconstruction and previous surgery on the affected knee.	Recruiting patients who fulfilled the inclusion criteria between October 2017 and October 2019	Group 1 - 34 Group 2 - 32	Group 1 - 13.5 $\pm$ 1.2 years (range 12-16 years) Group 2 - 13.8 $\pm$ 1.4 years (range 12-16 years)	Group 1 - 23/11 Group 2 - 20/12	26.6 $\pm$ 4.2 months for group 1 and 25.1 $\pm$ 2.2 months for group 2 - 7 patients were excluded: 3 lost at follow-up, 1 case, a cartilage lesion that required surgery was observed; and the remaining 3 cases had a knee multiligament reconstruction.

Moussa (2024)	Cohort study	ACLR alone - in cases of open physis - physeal-sparing quadrupled hamstring technique - in cases of closed physis were treated with quadrupled hamstring grafts (doubled gracilis and doubled semitendinosus or quadrupled semitendinosus) or bone–patellar tendon–bone procedures ACLR + LEAP Combined procedures (intraarticular and extraarticular): - In cases of open physes - partial transphyseal iliotibial band–based modified Macintosh procedures - closed physis - iliotibial band–based modified Macintosh procedures Or with the addition to the ACLR alone: lateral extra-articular tenodesis (LET) or anterolateral ligament (ALL) reconstruction using double-bundled gracilis	Inclusion criteria: patients <18 years of age; primary ACLR and 2 years of follow-up. Exclusion criteria: revision surgery; multiligamentous knee injury and refusal to participate in the study.	Multifactorial: factors taken into consideration included the type and level of the patient’s sport activity, patient demand, recurvatum, valgus knee alignment, chronicity of the lesion, presence of suturable meniscal lesion, and the severity of the preoperative rotational instability observed.	ACLR-alone - 132 ACLR + LEAP - 121	16.1 years (range, 12.9-17.9 years)	ACL R-alone – 67/65 ACL R + LEAP – 61/60	4.4 ± 1.6 years for the ACLR + LEAP group and 5.3 years ± 2.2 years for the ACLR-alone group – 15 patients lost to follow-up in the ACLR alone group and 26 lost to follow up in the ACLR + LEAP group
Retzky (2024)	Cohort study	ACLR Only – all-epiphyseal or transphyseal quadriceps tendon autograft reconstruction ACLR + LET - all-epiphyseal or transphyseal quadriceps tendon autograft reconstruction + Lateral extraarticular tenodesis.	Inclusion Criteria: primary ACLR; open distal femoral and proximal tibial physes and an MRI ordered for physeal monitoring at a minimum of 2 years postoperatively. Exclusion criteria: graft other than QTA (either HTA, bone-patellar-bone autograft, or iliotibial band [ITB] autograft, n = 33); revision ACLR (n	Not reported	ACLR Only – 13 ACLR + LET - 16	13.57 ± 1.12 years (all patients ≤	ACL R Only – 11/2 ACL R +	3.3 ± 1.0 years - 3.0 ± 1.1 years in the ACLR only group - 3.6 ± 0.8 years in the

			= 1) and if the knee MRI scan was obtained for a new injury (n = 11) (Figure 1).			18 years)	LET – 6/10	ACLR + LET group
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Table 1 – Study Characteristics for each study including study design, surgical techniques, inclusion and exclusion criteria, Criteria to perform a LEAP, Participant in each group, age, sex and follow-up time.

Study	Randomization process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Getgood 2020⁷³	Low	Some Concerns	Low	Low	Low	Some concerns

Table 2 – Risk-of-bias assessment of the included randomized studies using the ROB-2: A revised Cochrane risk-of-bias tool for randomized trial.

Study	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall Bias
Laboudie 2022	Moderate	Low	Low	Low	Moderate	Low	Low	Moderate
Monaco 2022	Moderate	Low	Low	Low	Moderate	Low	Low	Moderate
Perelli 2022	Moderate	Low	Low	Low	Low	Low	Low	Moderate
Moussa 2024	Moderate	Low	Low	Low	Moderate	Low	Low	Moderate
Retzky 2024	Moderate	Low	Low	Low	Low	Low	Low	Moderate

Table 3 – Risk-of-bias assessment of the included non-randomized studies using the ROBINS-I: Risk Of Bias In Non-randomised Studies – of Interventions

Study	Outcome measurement reported (either mean or median)	Experimental group	Control group	p-value
Laboudie 2022[30]	median	7	7	Not significant (> 0,05)
Monaco 2022[28]	median	7	6	0,010
Moussa 2024[31]	mean	7,2 ± 2,0	6,2 ± 2,3	0,042

Table 4 – Compilation of the results of the TAS. P-values in bold represent statistically significant differences.

Patient reported outcome measure	Experimental group	Control group	p-value
IKDC			
3 months	60,2 ± 0.4	62,9 ± 0.8	0,01
6 months	74,5 ± 0.7	76,7 ± 0.7	0,03
12 months	83,3 ± 0.8	85,0 ± 0.8	0,14
KOOS Pain			
3 months	78,8 ± 0.7	81,5 ± 0.7	0,007
6 months	85,7 ± 0.6	87,6 ± 0.6	0,02
12 months	90,2 ± 0.6	91,2 ± 0.6	0,20
KOOS Symptoms			
3 months	67,9 ± 0.9	71,8 ± 0.9	0,005
6 months	77,0 ± 0.8	80,7 ± 0.8	0,002
12 months	82,7 ± 0.8	83,1 ± 0.8	0,75
KOOS ADLs			
3 months	88,5 ± 0.6	91,0 ± 0.6	0,006
6 months	94,6 ± 0.4	96,1 ± 0.4	0,004
12 months	96,5 ± 0.4	97,2 ± 0.4	0,18
KOOS Recreation			
3 months	50,1 ± 1,0	54,8 ± 1.3	0,01
6 months	70,7 ± 1,1	74,2 ± 1.0	0,02
12 months	80,9 ± 1,1	82,5 ± 1.1	0,31
KOOS QOL			
3 months	42,4 ± 1,0	45,4 ± 1,0	0,03
6 months	54,4 ± 1,1	58,0 ± 1,1	0,02
12 months	65,2 ± 1,2	69,3 ± 1,2	0,02

Table 5 – PROs at 3-, 6- and 12-months post-surgery in the Getgood randomized controlled trial[27]. P-values in bold represent statistically significant differences.

Pivot-shift grade	Experimental group – Number of patients (percentage)	Control group - Number of patients (percentage)	p-value
0	24 (71,4)	55 (90,2)	0.008
1+	4 (11,4)	15 (24,6)	0,289
2+	2 (5,7)	0 (0,0)	0,141
3+	4 (11,4)	0 (0,0)	0,021

Table 6 – Pivot-shift grade test evaluation in the Monaco et. al. cohort study[28]. P-values in bold represent statistically significant differences.

Figures

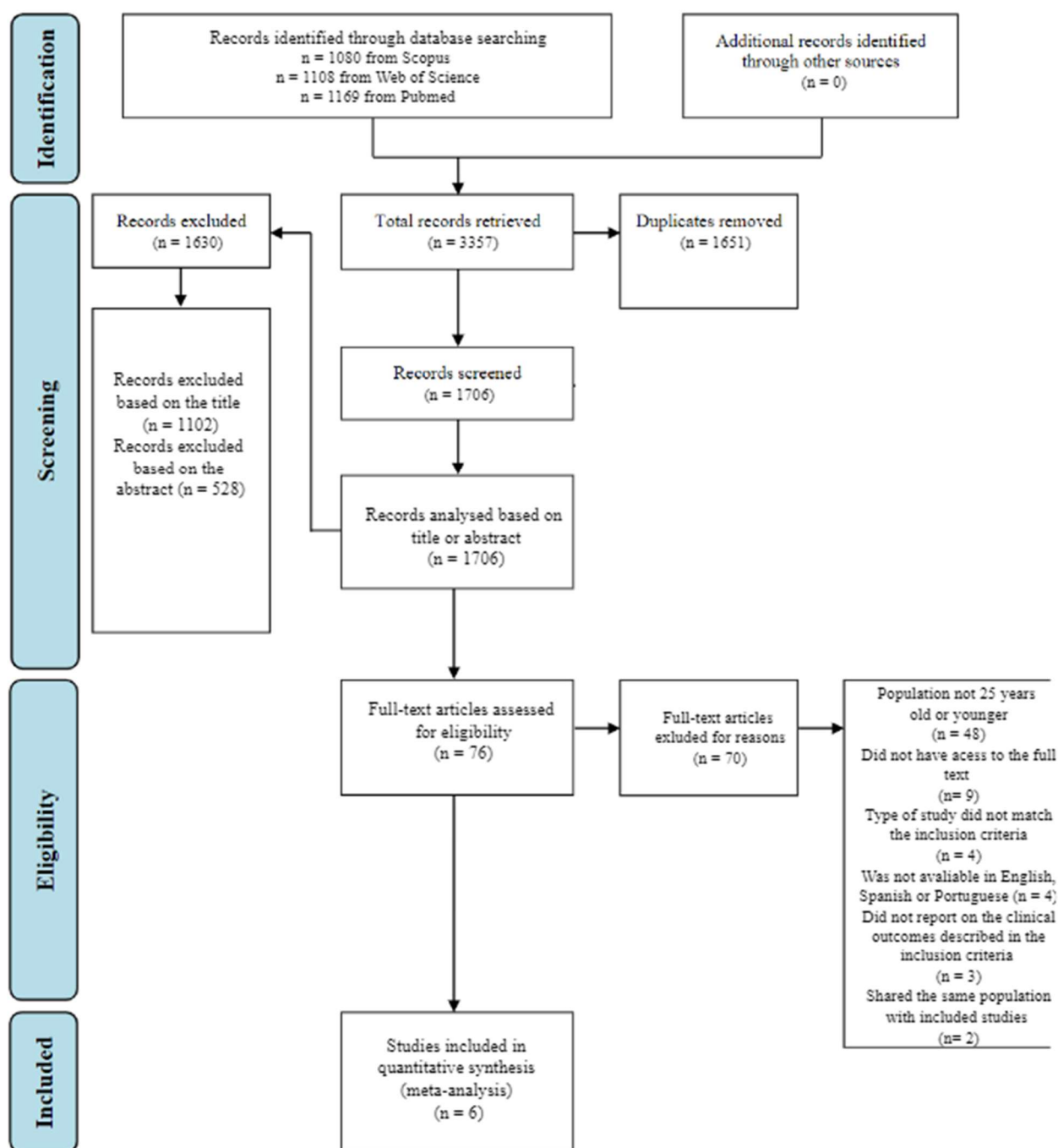


Fig. 1 – Flowchart of the followed study selection procedure according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) criteria

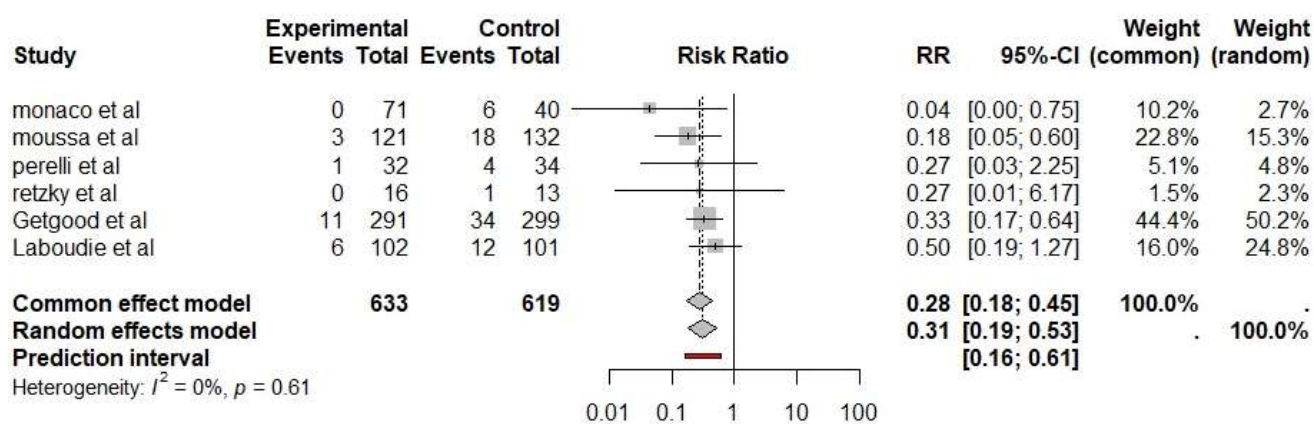


Fig. 2 – Forest plot showing graft failure rate for experimental versus control group.

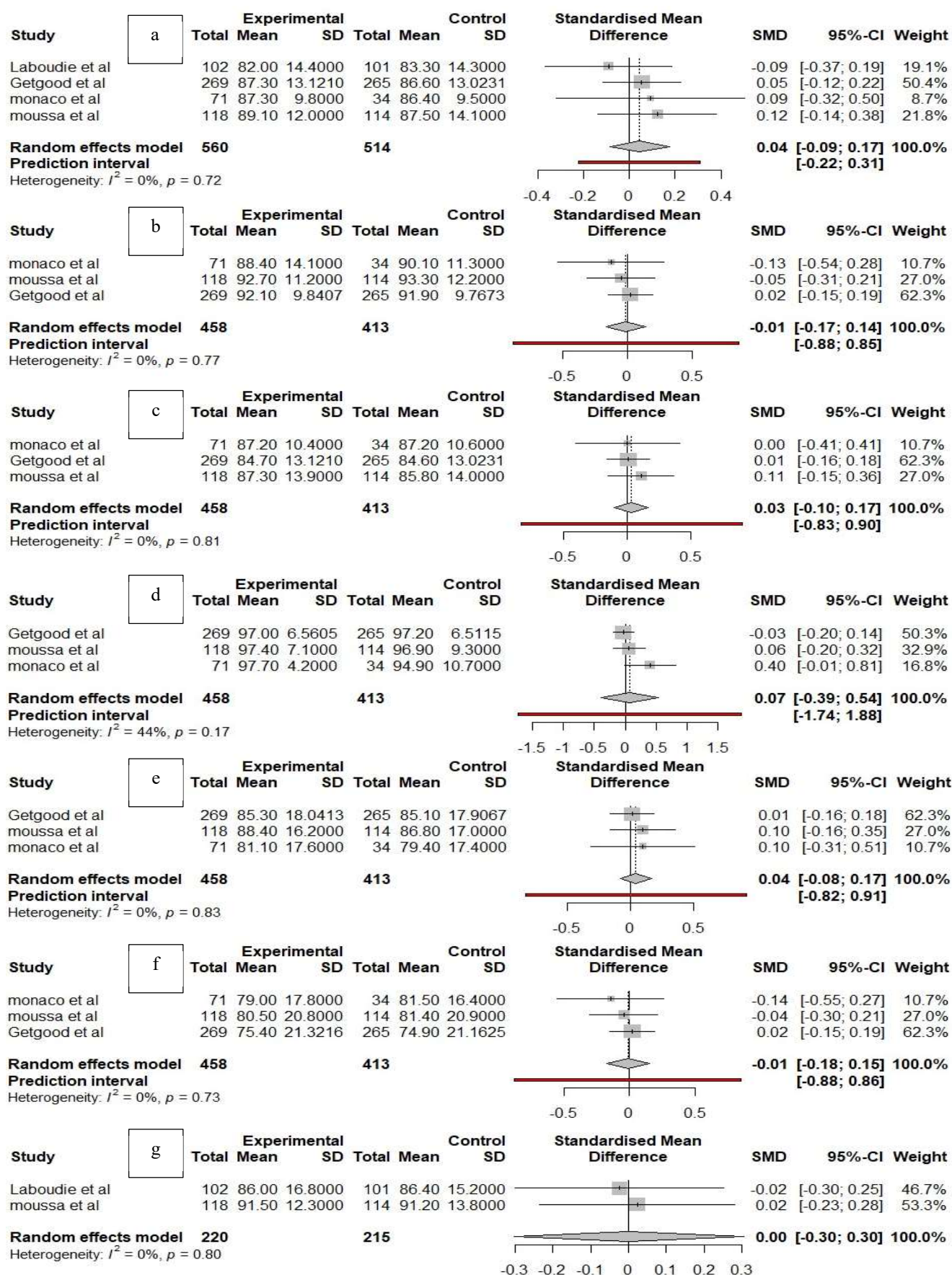


Fig. 3 - Forest plots showing PROs for experimental versus control group. a – IKDC-SKF; b – KOOS Pain; c – KOOS Symptoms; d – KOOS Activities of Daily Living; e – KOOS Sports and Recreation; f – KOOS Quality of Life; g – LKKS

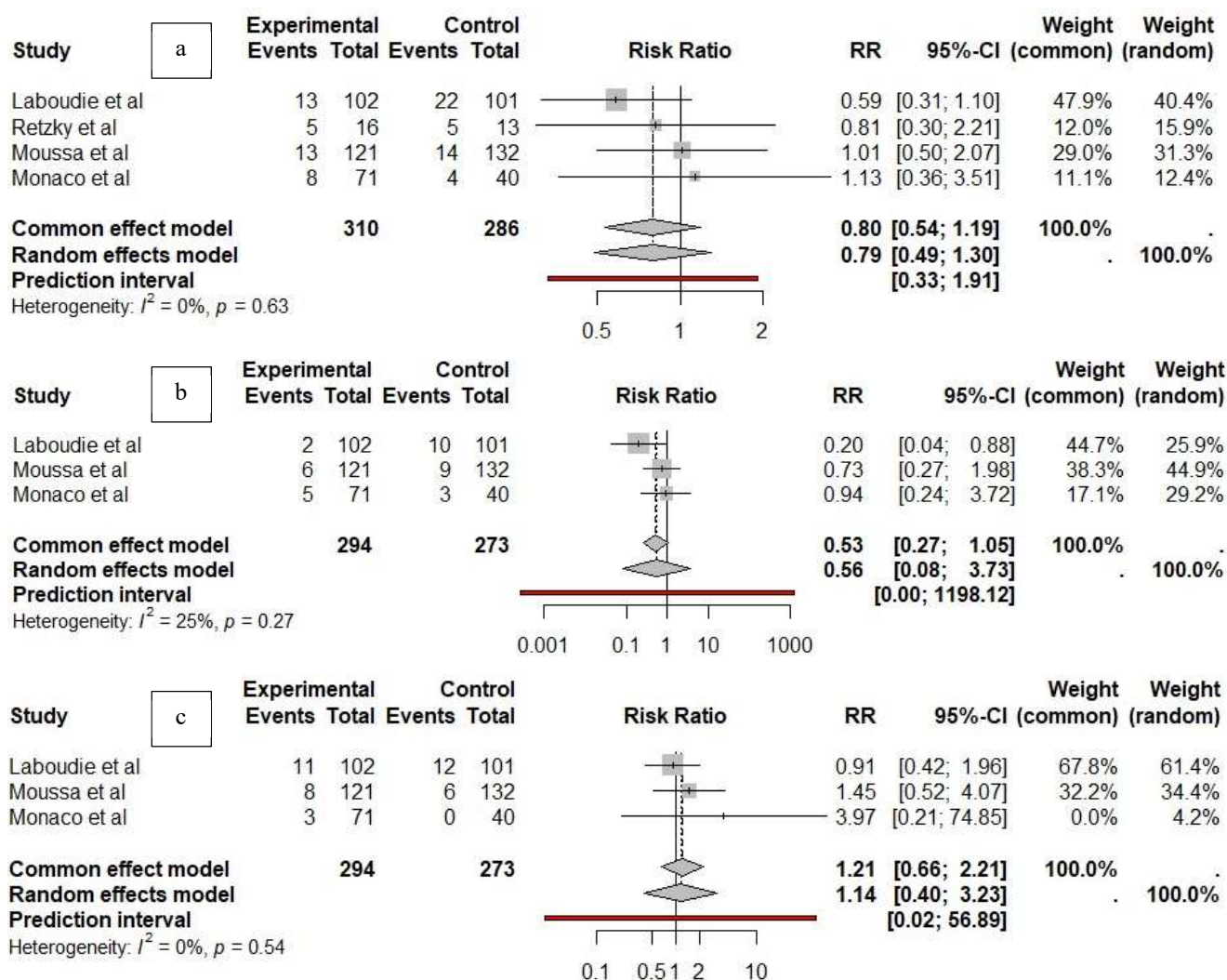


Fig. 4 – Forest plots showing complications rate for experimental versus control group. a – Non-graft related reoperations; b – Reoperations due to meniscal lesions and c – Reoperations due to causes other than graft failure and meniscal injuries in the previously operated knee.

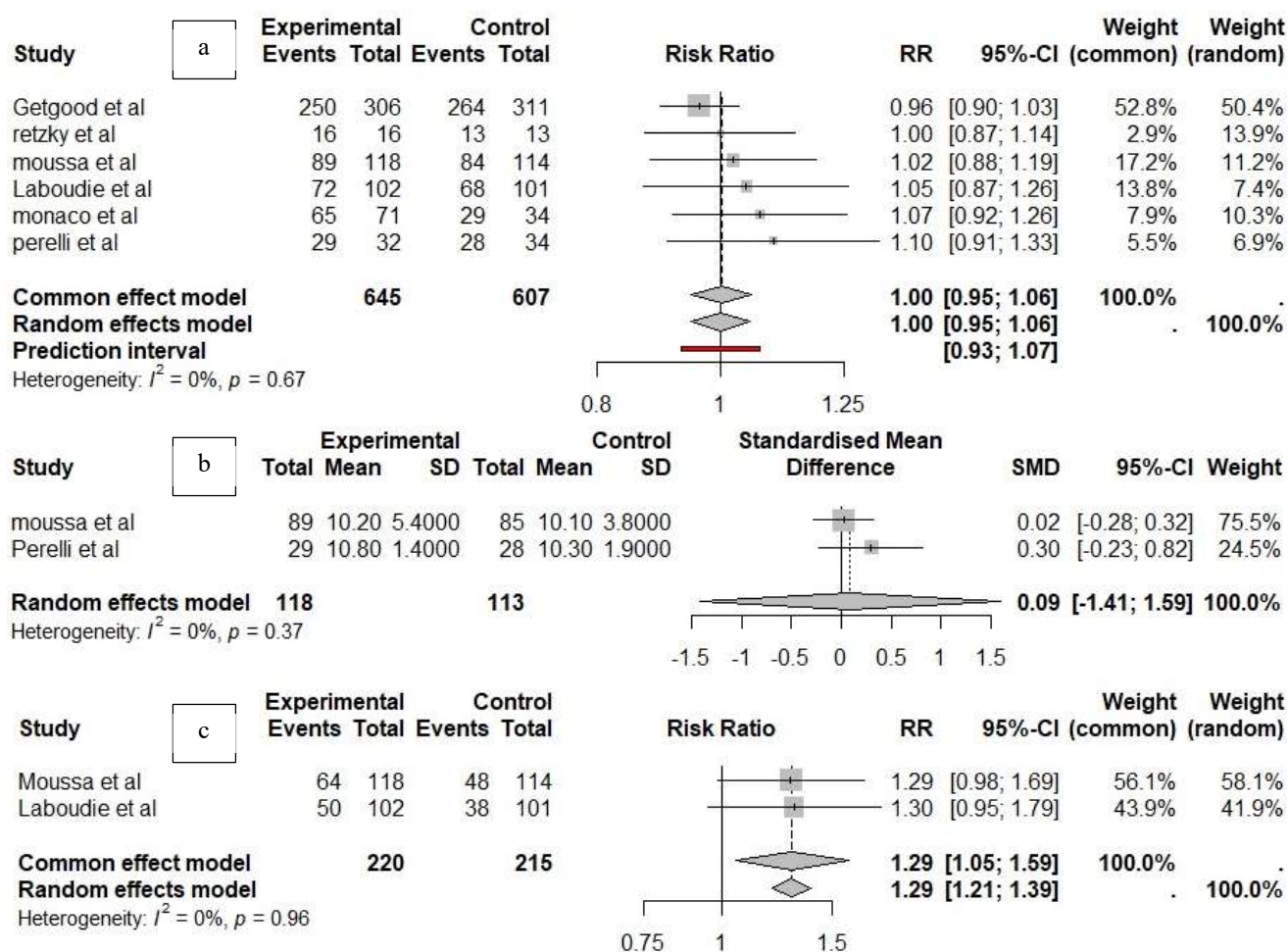


Fig. 5 – Forest plots showing Sports Related Outcomes for experimental versus control group. a – Return to sports Rate; b – time to return to sports and c – return to sports at the same level rate

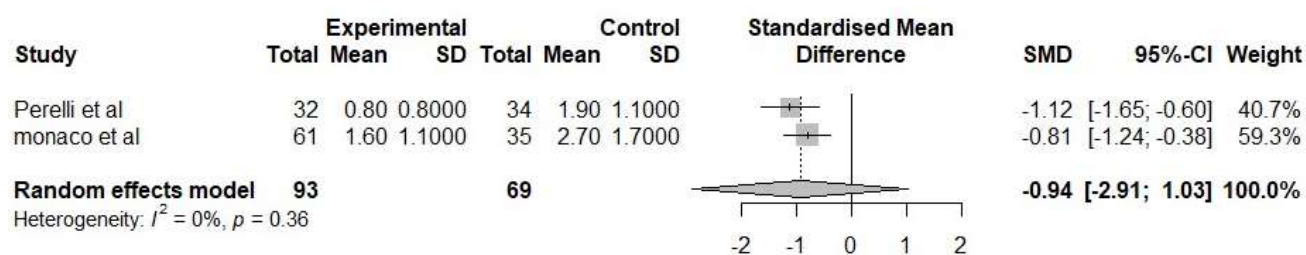


Fig. 6 – Forest plot showing side-to-side laxity differences in mm according to KT-1000 arthrometer for experimental versus control group.

Section/topic	#	Checklist item	Reported on page and paragraph/ table #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both. - MANDATÓRIO	Page 6 “Isolated ACL reconstruction vs combined with Lateral Extraarticular Procedures in patients 25 or younger: A Systematic-Review with meta-analysis.”
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. – SEGUIR RECOMENDAÇÕES DA REVISTA	Page 7 “ Introduction: ACL injuries are extremely prevalent in the younger and more active population. However, isolated ACL Reconstruction (ACLR) results are still not good enough with young patients continuing to report high risk of graft failure. Purpose: This study aims to assess if the addition of a Lateral Extraarticular Procedure (LEAP) leads to better clinical outcomes ACLR in patients 25 or younger. Methods: This study was performed according to the PRISMA guidelines. The literature search, data extraction, and quality assessment were conducted by 2 independent reviewers using PubMed, SCOPUS, and Web of Science through to February 14, 2024. We included studies comparing isolated ACLR to ACLR with LEAPs in patients 25 or younger that focused on graft failure rate or patient-reported outcomes (PROs). Results: Six studies (one randomized controlled trial and five cohort studies) involving 1280 patients were included. Our meta-analysis showed that the addition of a LEAP significantly reduced graft failure rates (RR = 0,31; 95% C.I. 0,19 to 0,53; I2 = 0) and lead to higher return to sports at the same level (RR = 1.2943; 95% C.I. 1.2051 - 1.3901; I2 = 0%), one of the studies also reported better pivot-shift test results when a LEAP was added. On the contrary, one study reported worse patient reported outcomes (PROs) in the first months after surgery with the addition of a LEAP. No statistically significant differences were found in the other remaining outcomes. Conclusion: Adding a LEAP to ACLR in patients 25 or younger appears to lower graft failure rate without altering long-term PROs. Despite encouraging results, the reduced number of studies included in our review highlights the need for more research, particularly randomized controlled trials to further assert being younger than 25 as criteria for the addition of a LEAP.”
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. – MANDATÓRIO <i>O rationale corresponde à justificação da importância da revisão sistemática</i>	Page 8 “ However, it appears that not all patients benefit from performing a LEAP and with potential overconstraint of the knee[16] and other adverse effects [17-21], it becomes essential to define clear indications for these procedures. Vundelinckx et al.[22] and Sonnery-Cottet et al.[23] recently attempted to identify the patients that would benefit the most from the addition of a LEAP and both considered being ≤ 25 as potential criteria for these procedures.

Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). - MANDATÓRIO	Page 8 “ The aim of this review is to report on clinical outcomes of adding either a LET or an ALLR in this population to answer the question: Should we add LEAPs to ACLR in patients 25 or younger?”
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. – FACULTATIVO	No previous protocol was developed
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. – MANDATÓRIO <i>É altamente recomendado, de acordo com as boas práticas da Cochrane, que não sejam aplicados critérios de exclusão baseados na língua e/ou data de publicação dos estudos.</i>	Page 9 “ We included studies that (1) compared isolated ACLR to ACLR with a LEAP (LET or ALLR) (randomized controlled trials, prospective or retrospective cohort studies); (2) the population consisted of people aged 25 or younger; (3) reported on at least one of the following outcomes: Lysholm Knee Scoring Scale (LKSS); International Knee Documentation Committee Subjective Knee Form (IKDC-SKF); Knee injury and Osteoarthritis Outcome Score (KOOS), Tegner Activity Scale (TAS) or Graft failure; (4) had a minimum follow-up period of 24 months and (5) was written in English, Spanish or Portuguese language. Studies were excluded if they met the following criteria: (1) studies not performed on humans; (2) cadaveric studies; (3) studies about secondary ACLR, ACL revision surgeries or the addition of a LEAP following an initial isolated ACLR; (4) studies that reported on the simultaneous reconstruction of the ACL and the posterior cruciate ligament or the lateral collateral ligament and (5) studies that applied different intraarticular procedures in the isolated ACLR group when compared to the ACLR with LEAP expecting different outcomes (for instance a study comparing double bundle ACLR alone with single bundle ACLR plus LET would be excluded however studies comparing isolated hamstring graft intraarticular ACLR with a modified Macintosh procedure that combined both the intraarticular and extraarticular procedures using the iliotibial band were still included”
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 9 “ A comprehensive search was conducted across multiple databases (PubMed, SCOPUS and Web of Science) from the date of database inception through to February 14 of 2024.”

		– MANDATÓRIO <i>Em consonância com as boas práticas da Cochrane, é mandatório que se verifique pesquisa em pelo menos duas bases de pesquisa bibliográfica (idealmente, deverão ser pesquisadas duas bases generalistas e uma específica da área). No caso de revisões sistemáticas de estudos experimentais/ensaio clínico aleatorizados, é altamente recomendado que uma das bases pesquisadas corresponda à CENTRAL ou a bases de ensaios clínicos como a ClinicalTrials.gov. Estudos de revisão da literatura em que a pesquisa decorra numa única base de dados não serão classificados como revisões sistemáticas.</i>	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. – MANDATÓRIO <i>A query de pesquisa deve ser obrigatoriamente disponibilizada. A utilização de filtros de pesquisa da InterTASC é altamente recomendada (https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/home)</i>	Page 9 “ The Medical Subject Headings and Boolean operator terms used for the search were [(“Anterior cruciate ligament reconstruction” OR “ACL reconstruction”) AND (“Extraarticular” OR “Anterolateral ligament” OR “Lateral Extraarticular Tenodesis” OR “Macintosh” OR “Lemaire” OR “Ellison”)]”
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). – MANDATÓRIO <i>As fases de selecção dos estudos primários devem ser descritas. Em consonância com as boas práticas da Cochrane, é mandatório que o processo</i>	Page 9 “ Two authors (AFC and OBS), following exclusion of the duplicates, first reviewed the title and abstract of each article to exclude those that did not meet the requirements. Afterwards, the full texts of the remaining articles were reviewed. Any conflicts on article inclusion were resolved by discussion between the two.”

		<i>de selecção envolva duas fases (fase de rastreio, em que os registos são seleccionados por título e abstract, e fase de inclusão, na qual se procede à leitura integral dos full texts). Em cada uma destas fases, o processo de selecção deve mandatoriamente envolver dois investigadores actuando de forma independente.</i>	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. – MANDATÓRIO <i>Trata-se de descrever de que forma se procedeu à extracção de dados dos estudos primários. Em consonância com as boas práticas da Cochrane, tal processo deverá envolver dois investigadores de forma independente.</i>	Page 9 “ The relevant data from eligible studies was extracted by two independent examiners (AFC and JPM).” Page 10 “ Any discrepancies in data extracted were resolved by discussion between the two reviewers..”
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. – MANDATÓRIO <i>Trata-se de descrever as variáveis para as quais foi obtida informação.</i>	Pages 9-10 “ The extracted data included study demographic data (study design, surgical techniques, inclusion and exclusion criteria, criteria used to perform the LEAP, sex, mean age, number of participants in each group and follow-up time) and the following outcomes: (1) graft failure rate; (2) patient reported outcomes (PROs) at 3, 6, 12 months and at final follow-up including IKDC-SKF, KOOS, LKKS and TAS; (3) return to sports rate, time to return to sports and rate of return to sports at the same level; (4) non-graft related reoperations rate, rate of reoperations due to meniscal injury and rate of reoperations due to causes other than graft failure and meniscal injury in the previously operated knee; (5) pivot-shift test results and (6) side-to-side laxity differences according to the KT-1000 arthrometer.”
Risk of bias in individual studies / Risk of bias across studies	12/ 15	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data	Page 10 “ The risk-of-bias of the included studies was independently assessed by 2 examiners (AFC and OBS) using the ROB-2: A revised Cochrane risk-of-bias tool for randomized trials[24] and ROBINS-I: Risk Of Bias In Non-randomised Studies - of Interventions[25]. If there was a disagreement, the two examiners came to a decision by discussion.”

		synthesis. – MANDATÓRIO <i>Em todas as revisões sistemáticas, deverá existir um processo de avaliação da qualidade dos estudos primários. No caso de revisões sistemáticas de estudos experimentais/ensaio clínicos aleatorizados, a aplicação dos critérios de risco de viés (Risk of Bias) da Cochrane é altamente recomendada. No caso de revisões sistemáticas de estudos observacionais, poderão ser seguidos os critérios ROBINS ou os critérios dos National Institutes of Health (https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools).</i>	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means). – FACULTATIVO. APENAS NECESSÁRIO SE FOR FEITA META-ANÁLISE	Page 10 “The risk ratio (RR) and its corresponding 95% CI were calculated for dichotomous data. For continuous variables assessed in the same way between studies, we calculated the mean difference (MD) and 95% C.I.”
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis. – FACULTATIVO. APENAS NECESSÁRIO SE FOR FEITA META-ANÁLISE	Page 10 “Heterogeneity was assessed by the I^2 statistic and an I^2 value >50% was considered to indicate significant heterogeneity. Since we allowed for different population characteristics to be included and surgical techniques to be performed, possibly leading to substantial between-studies variance, we opted to use the random effects model for the meta-analysis.”
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. – FACULTATIVO. APLICÁVEL APENAS SE FOR FEITA META-ANÁLISE	Page 10 “No sensitivity analysis or subgroup analysis was performed due to lack of studies reporting each outcome and, for the same reason, publication bias was not assessed according to funnel-plots.”
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally	Page 11 “The initial literature search resulted in 3357 total studies. After duplicates were removed 1706 articles were screened for their title and abstract with further removal of 1630 articles. The remaining 76 articles were read in their entirety and 6 of

		with a flow diagram. – MANDATÓRIO	those studies were included in this review. The detailed results of the search for relevant literature based on the strategy described above can be found in Figure 1.” Figure 1.
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. – MANDATÓRIO	Page 11 “ A total of six articles[26-31] were included: 1 randomized controlled trial[26] and 5 cohort studies[27-31]. There was a total of 1280 patients enrolled for this systematic review and meta-analysis with 632 patients enrolled in the control group (isolated ACLR) and 648 patients enrolled in the experimental group (ACLR with a LEAP). The table of study characteristics showed different criteria for eligibility of populations, different criteria for performing the LEAP and different surgical procedures for the included articles. – Table 1.” Table 1.
Risk of bias within and across studies	19/ 22	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). – MANDATÓRIO	Page 11 “ The quality assessment for the randomized controlled trial [26] was performed using the ROB-2 tool that revealed some concerns in the overall risk-of-bias - Table 2. The quality of the remaining 5 non-randomized trial studies[27-31] was assessed by the ROBINS-I tool (Risk Of Bias In Non-randomized Studies – of Interventions) with all of the studies reporting an overall moderate risk-of-bias - Table 3..” Tables 2 and 3 No outcome level assessments were performed
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. – FACULTATIVO. APLICÁVEL APENAS SE FOR FEITA META-ANÁLISE	Tables 4, 5 and 6. Figures 2, 3, 4, 5 and 6
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency. – FACULTATIVO.	Page 11 “The graft rupture rate was analysed in all studies [26-31] including 633 patients in the experimental group and 619 patients in the control group. Analysis indicated no significant heterogeneity and the graft rupture rate was significantly lower

		MANDATÓRIO APENAS SE FOR FEITA META-ANÁLISE in the experimental group compared to the control group (RR = 0,31; 95% C.I. [0,19; 0,53]; I2 = 0). - Figure 2.” Page 11 “IKDC-SKF was analysed in four studies[26, 27, 29, 30] including 560 patients in the experimental group and 514 patients in the control group. There were no significant differences between groups and no significant heterogeneity was detected (SMD: 0,04; 95% C.I. [-0,09; 0,17]; I2 = 0) - Figure 3a” Page 11-12 “The KOOS score was analysed in three studies[26, 27, 30] including 560 patients in the experimental group and 514 patients in the control group. No significant heterogeneity and no significant differences between groups were found for the KOOS Pain, KOOS Symptoms, KOOS Activities of Daily Living, KOOS Sports and Recreation and KOOS Quality of Life. (KOOS Pain: SMD = -0,01; 95% C.I. [-0,17; 0,14], I2 = 0%; KOOS Symptoms: SMD = 0,03, 95% C.I. [-0,10; 0,17], I2 = 0%; KOOS Activities of daily living: SMD = 0,07, 95% C.I. [-0,39; 0,54], I2 = 44%; KOOS Sports and Recreation: SMD = 0,04; 95% C.I. [-0,08; 0,17], I2 = 0%; KOOS Quality of Life: SMD = -0,01; 95% C.I. [-0,18; 0,15], I2 = 0%) – Figure 3b, 3c, 3d, 3e, 3f.” Page 12 “The LKKS was analysed in two studies[29, 30] including 220 patients in the experimental group and 215 patients in the control group. No significant heterogeneity and no significant differences between groups were reported. (SMD = 0,00; 95% C.I. [-0,30; 0,30], I2 = 0) - Figure 3g” Page 12 “The non-graft related reoperation rate was analysed in four studies[27, 29-31] including 310 patients in the experimental group and 286 patients in the control group. In three studies[27, 29, 30] including 294 patients in the experimental group and 273 patients in the control group, it was possible to further analyse the reoperations due to meniscal injuries and the reoperations due to causes other than graft failure and meniscal injury in the previously operated knee (including arthrolysis, cyclops, hardware removal and infection). Analysis indicated no significant heterogeneity between groups (only the analysis of reoperations due to meniscal lesion had a I2 ≠ 0 but it was still < 50%) and, despite the rate of non-graft related reoperation (RR = 0.7938; 95% C.I. [0.4858; 1.2973]; I2 = 0%) and reoperation due to meniscal lesions (RR = 0.5597; 95% C.I. [0.0841; 3.7259]; I2 = 25%) being lower and the rate of reoperations due to causes other than graft failure and meniscal injury in the previously operated knee (RR = 1.1361; 95% C.I. [0.3997; 3.2289]; I2 = 0%) being higher in the experimental group, the random effects model showed no statistically significant differences. - Figure 4.” Pages 12-13 “The return to sports rate was analysed in all studies[26-31], including 645 patients in the experimental group and 607 patients in the control group; the time
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			to return to sports was analysed in two studies [28, 30], including 118 patients in the experimental group and 113 patients in the control group and the rate of return to the same level of sports was analysed in another two studies[29, 30], including 220 patients in the experimental group and 215 patients in the control group. Analysis indicated no significant heterogeneity and no significant differences between groups in either the return to sports rate (RR = 1,00; 95% C.I. [0,95; 1,06]; I2 = 0%) or the time to return to sports (SMD = 0,09; 95% C.I. [-1,41; 1,59]; I2 = 0%). However, the return to the same level of sport was significantly higher in the experimental group (RR = 1.2943; 95% C.I. [1.2051; 1.3901]; I2 = 0%). - Figure 5.” Page 13 “The side-to-side laxity differences assessed by the KT-1000 arthrometer were reported on two studies [27, 28]. A meta-analysis was performed with the experimental group reporting a not statistically significant lower side-to-side laxity difference (SMD = -0.9376; 95% C.I.[-2.9066; 1.0314]). - Figure 6” . Figures 2, 3, 4, 5 and 6
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). – FACULTATIVO. APLICÁVEL APENAS SE FOR FEITA META-ANÁLISE	No additional analyses were performed
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). – MANDATÓRIO	Page 14 “ Our meta-analysis reported statistically significant lower graft rupture rate in patients in our experimental group when compared to the control group showing that similarly to the general population, the subpopulation of patients younger than 25 also appears to benefit from having a LEAP when it comes to graft failure.” Page 14 “ For all the PROs we included in our study, our meta-analysis showed no statistically significant differences between the experimental and control group. However, for the TAS, 2 of the 3 studies we included in our review showed significant superiority favouring our experimental group.” Page 15 “The study by Getgood et al.[26] further reported on PROs at 3,6 and 12 months with the control group showing significantly better results in the: IKDC-SKF at 3 and 6 months, KOOS Pain at 3 and 6 months, KOOS symptoms at 3 and 6 months,

			KOOS ADL at 3 and 6 months, KOOS Recreation at 3 and 6 months and KOOS QOL at 3,6 and 12 months. By analysing the results of our study and further assessing other systematic reviews it appears that while the PROs eventually evolve to be not worse or even better with the addition of a LEAP to ACLR, in the initial months following the surgery these procedures lead to worse PROs with more pain and symptoms and less activity and quality of life.” Page 15 “ Our meta-analysis showed a lower reoperation rate due to meniscal lesion and higher reoperation rate due to causes other than graft failure and meniscal lesions in the previously operated knee (including arthrolysis, cyclops, hardware removal and infections) in our experimental group. However, none of the differences reported were sufficient to translate into statistical significance. Our review indicates that while there might be an increased risk of some complications when a LEAP is performed, these procedures also appear to have a protective factor in secondary meniscal injuries after ACLR (possibly explained by the association between meniscal lesions and residual knee laxity[40] - as we will discuss further ahead adding a LEAP appears to lower residual knee laxity).” Page 15 “ Our meta-analysis showed no statistically significant differences in return to sports rate and time to return to sports. “ Page 15 “Our meta-analysis reported a higher return to sports at the same level in our experimental group, despite only 2 studies being included, suggesting that the addition of a LEAP could potentially lead to better results in the level of sports the patients return to.” Page 16 “ Our meta-analysis showed that the addition of a LEAP leads to lower results in side-to-side laxity differences according to the KT-1000.”
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). – MANDATÓRIO	Page 16 and 17 This study had several limitations affecting the strength of the conclusions that can be drawn from this analysis. Primarily, the scarcity of studies on the subject lead to only six studies being included with only one being a randomized controlled trial and the other 5 being cohort studies therefore having the limitations inherent to these study designs. Additionally, our risk-of-bias analysis of the included studies indicated some reasons for concern for the randomized controlled trial and

		moderate overall risk-of-bias for the remaining cohort studies. Furthermore, the patients included in the studies had factors other than age alone possibly affecting the results. This is particularly important since the study with more weight on our meta-analysis (the study by Getgood et al.[26]) only included patients with high anterior knee laxity and a recent study by Eggeling et al. [46] (despite its retrospective nature and small sample) suggested that adding a LEAP to revision ACLR in patients with low-grade anterior knee laxity did not influence PROs or graft failure rates. Also complicating our analysis were the inclusion of all surgical procedures with potential differences in outcomes with different graft types (patellar tendon autograft, hamstring autograft, allografts or others), surgical techniques (such as double bundle and single bundle procedures) and LEAPs performed (LET or ALLR and different techniques for each of these procedures) not being analysed. Another limitation of the review were the differences in skeletal maturity between studies due to potential risk of growth arrest, limb-length discrepancies, and angular deformities when ACLR is performed on open physis [47]. In these cases, nonsurgical treatment or delayed reconstruction has been associated with worse outcomes, however questions remain on whether transphyseal, physeal-sparing or all-epiphyseal techniques are preferred for ACLR [47] and while the addition of a LEAP appears safe in these populations, questions remain on long term complications[48]. This review did not report on long term outcomes with only 24 months of follow-up being enough to be included in our study and therefore not reporting if the improvements caused by the addition of a LEAP are kept following the initial years after the surgery. The lack of long-term studies also made it impossible to analyse the rate of osteoarthritis, particularly important since addition of a LET appears to lead to overconstraint of the knee[15]. Other literature reporting on osteoarthritis shows no consensus with Devitt et al.[49] showing no increase in osteoarthritis with a LET but Castoldi et al.[50] finding that patients who underwent ACLR with LET had a greater rate of lateral compartment osteoarthritis compared with patients who underwent isolated ACLR. By detailing these limitations, we are further reinforcing the need for future research to focus on randomized controlled trials in younger cohorts, with no other factors except for age being considered for the inclusion in the study. More randomized controlled trials in young cohorts should also focus on a longer follow-up term to see whether the improved are kept on longer term follow-ups and to report on whether the addition of a LEAP leads to higher rates of osteoarthritis. If more studies further suggest that the addition of a LEAP leads to better clinical outcomes, then there needs to be a focus
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			on randomized controlled trials comparing different surgical techniques and grafts to find the better intra and extraarticular ACLR in young patients for open and for closed physis. “”
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research. – MANDATÓRIO	Page 16 “This systematic review and meta-analysis showed lower graft failure rate and higher return to the same level of sport when a LEAP was performed. Despite our review suggesting worse PROs in the initial months when a LEAP is added, our meta-analysis showed no statistically significant differences in PROs at final follow-up with only TAS reporting significantly superior scores in 2 out of 3 studies with the addition of these procedures. Our review also suggests better pivot-shift test results with the addition of these procedures. These results are supported by other systematic reviews and studies and by limiting the population of the study to young patients 25 years or younger, a population at high risk of graft failure, it further justifies the inclusion of young age as possible criteria for the addition of a LEAP. More randomized controlled trials should focus on the addition of a LEAP in patients 25 or younger and longer follow-ups are needed in other to further solidify the conclusions of this study. .”
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. – SEGUIR RECOMENDAÇÕES DA REVISTA	Page 6 “ Funding: No funding was received for conducting this study Competing interests: The authors have no relevant financial or non-financial interests to disclose.”

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1. Negotiation research spans many disciplines [3].
2. This result was later contradicted by Becker and Seligman [5].
3. This effect has been widely studied [1-3, 7].

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- Book chapter

Brown B, Aaron M (2001) The politics of nature. In: Smith J (ed) *The rise of modern genomics*, 3rd edn. Wiley, New York, pp 230-257

- Online document

Cartwright J (2007) Big stars have weather too. IOP Publishing PhysicsWeb. <http://physicsweb.org/articles/news/11/6/16/1>. Accessed 26 June 2007

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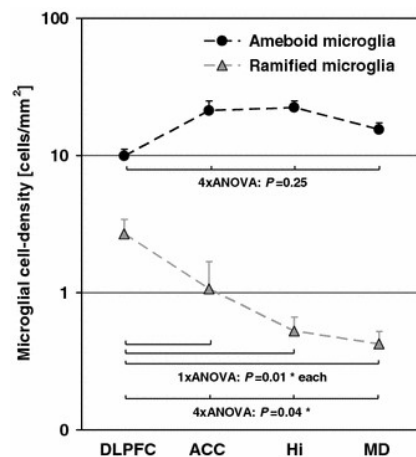
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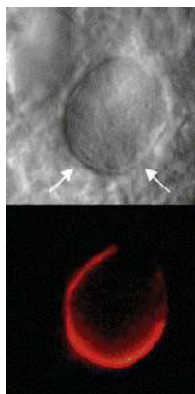
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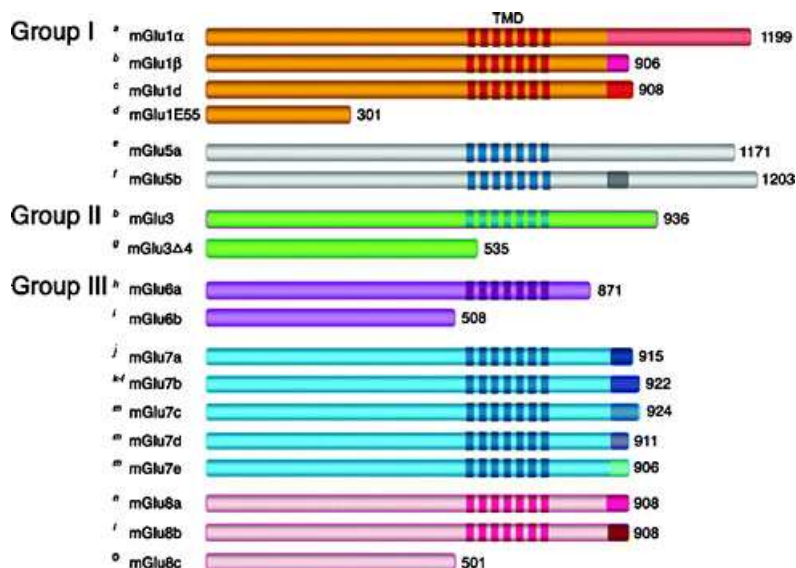


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Examples:

Organism: Filip1tm1a(KOMP)Wtsi RRID:MMRRC_055641-UCD

Cell Line: RST307 cell line RRID:CVCL_C321

Antibody: Luciferase antibody DSHB Cat# LUC-3, RRID:AB_2722109

Plasmid: mRuby3 plasmid RRID:Addgene_104005

Software: ImageJ Version 1.2.4 RRID:SCR_003070

RRIDs are provided by the Resource Identification Portal. Many commonly used research resources already have designated RRIDs. The portal also provides authors links so that they can quickly register a new resource and obtain an RRID.

Clinical Trial Registration

The World Health Organization (WHO) definition of a clinical trial is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". The WHO defines health interventions as "A health intervention is an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions" and a health-related outcome is generally defined as a change in the health of a person or population as a result of an intervention.

To ensure the integrity of the reporting of patient-centered trials, authors must register prospective clinical trials (phase II to IV trials) in suitable publicly available repositories. For example www.clinicaltrials.gov or any of the primary registries that participate in the WHO International Clinical Trials Registry Platform.

The trial registration number (TRN) and date of registration should be included as the last line of the manuscript abstract.

For clinical trials that have not been registered prospectively, authors are encouraged to register retrospectively to ensure the complete publication of all results. The trial registration number (TRN), date of registration and the words 'retrospectively registered' should be included as the last line of the manuscript abstract.

Standards of reporting

Springer Nature advocates complete and transparent reporting of biomedical and biological research and research with biological applications. Authors are recommended to adhere to the minimum reporting guidelines hosted by the EQUATOR Network when preparing their manuscript.

Exact requirements may vary depending on the journal; please refer to the journal's Instructions for Authors.

Checklists are available for a number of study designs, including:

Randomised trials (CONSORT) and Study protocols (SPIRIT)

Observational studies (STROBE)

Systematic reviews and meta-analyses (PRISMA) and protocols (Prisma-P)

Diagnostic/prognostic studies (STARD) and (TRIPOD)

Case reports (CARE)

Clinical practice guidelines (AGREE) and (RIGHT)

Qualitative research (SRQR) and (COREQ)

Animal pre-clinical studies (ARRIVE)

Quality improvement studies (SQUIRE)

Economic evaluations (CHEERS)

Summary of requirements

The above should be summarized in a statement and placed in a 'Declarations' section before the reference list under a heading of 'Ethics approval'.

Examples of statements to be used when ethics approval has been obtained:

- All procedures performed in studies involving human participants were 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. The study was approved by the Bioethics Committee of the Medical University of A (No. ...).
- This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University B (Date.../No. ...).
- Approval was obtained from the ethics committee of University C. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.
- The questionnaire and methodology for this study was approved by the Human Research Ethics committee of the University of D (Ethics approval number: ...).

Examples of statements to be used for a retrospective study:

- Ethical approval was waived by the local Ethics Committee of University A in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.
- This research study was conducted retrospectively from data obtained for clinical purposes. We consulted extensively with the IRB of XYZ who determined that our study did not need ethical approval. An IRB official waiver of ethical approval was granted from the IRB of XYZ.
- This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Human Investigation Committee (IRB) of University B approved this study.

Examples of statements to be used when no ethical approval is required/exemption granted:

- This is an observational study. The XYZ Research Ethics Committee has confirmed that no ethical approval is required.
- The data reproduced from Article X utilized human tissue that was procured via our Biobank AB, which provides de-identified samples. This study was reviewed and deemed exempt by our XYZ Institutional Review Board. The BioBank protocols are in accordance with the ethical standards of our institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Authors are responsible for correctness of the statements provided in the manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right to reject submissions that do not meet the guidelines described in this section.

Informed consent

All individuals have individual rights that are not to be infringed. Individual participants in studies have, for example, the right to decide what happens to the (identifiable) personal data gathered, to what they have said during a study or an interview, as well as to any photograph that was taken. This is especially true concerning images of vulnerable people (e.g. minors, patients, refugees, etc) or the use of images in sensitive contexts. In many instances authors will need to secure written consent before including images.

Identifying details (names, dates of birth, identity numbers, biometrical characteristics (such as facial features, fingerprint, writing style, voice pattern, DNA or other distinguishing characteristic) and other information) of the participants that were studied should not be published in written descriptions, photographs, and genetic profiles unless the information is essential for scholarly purposes and the participant (or parent/guardian if the participant is a minor or incapable or legal representative) gave written informed consent for publication. Complete anonymity is difficult to achieve in some cases. Detailed descriptions of individual participants, whether of their whole bodies or of body sections, may lead to disclosure of their identity. Under certain circumstances consent is not required as long as information is anonymized and the submission does not include images that may identify the person.

Informed consent for publication should be obtained if there is any doubt. For example, masking the eye region in photographs of participants is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic profiles, authors should provide assurance that alterations do not distort meaning.

Exceptions where it is not necessary to obtain consent:

- Images such as x rays, laparoscopic images, ultrasound images, brain scans, pathology slides unless there is a concern about identifying information in which case, authors should ensure that consent is obtained.
- Reuse of images: If images are being reused from prior publications, the Publisher will assume that the prior publication obtained the relevant information regarding consent. Authors should provide the appropriate attribution for republished images.

Consent and already available data and/or biologic material

Regardless of whether material is collected from living or dead patients, they (family or guardian if the deceased has not made a pre-mortem decision) must have given prior written consent. The aspect of confidentiality as well as any wishes from the deceased should be respected.

Data protection, confidentiality and privacy

When biological material is donated for or data is generated as part of a research project authors should ensure, as part of the informed consent procedure, that the participants are made aware what kind of (personal) data will be processed, how it will be used and for what purpose. In case of data acquired via a biobank/biorepository, it is possible they apply a broad consent which allows research participants to consent to a broad range of uses of their data and samples which is regarded by research ethics committees as specific enough to be considered “informed”. However, authors should always check the specific biobank/biorepository policies or any other type of data provider policies (in case of non-bio research) to be sure that this is the case.

Consent to Participate

For all research involving human subjects, freely-given, informed consent to participate in the study must be obtained from participants (or their parent or legal guardian in the case of children under 16) and a statement to this effect should appear in the manuscript. In the case of articles describing human transplantation studies, authors must include a statement declaring that no organs/tissues were obtained from prisoners and must also name the institution(s)/clinic(s)/department(s) via which organs/tissues were obtained. For manuscripts reporting studies involving vulnerable groups where there is the potential for coercion or where consent may not have been fully informed, extra care will be taken by the editor and may be referred to the Springer Nature Research Integrity Group.

Consent to Publish

Individuals may consent to participate in a study, but object to having their data published in a journal article. Authors should make sure to also seek consent from individuals to publish their data prior to submitting their paper to a journal. This is in particular applicable to case studies. A consent to publish form can be found [here](#). (Download docx, 36 kB)

Summary of requirements

The above should be summarized in a statement and placed in a 'Declarations' section before the reference list under a heading of 'Consent to participate' and/or 'Consent to publish'. Other declarations include Funding, Competing interests, Ethics approval, Consent, Data and/or Code availability and Authors' contribution statements.

Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

Sample statements for "Consent to participate":

Informed consent was obtained from all individual participants included in the study.

Informed consent was obtained from legal guardians.

Written informed consent was obtained from the parents.

Verbal informed consent was obtained prior to the interview.

Sample statements for "Consent to publish":

The authors affirm that human research participants provided informed consent for publication of the images in Figure(s) 1a, 1b and 1c.

The participant has consented to the submission of the case report to the journal.

Patients signed informed consent regarding publishing their data and photographs.

Sample statements if identifying information about participants is available in the article:

Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

Authors are responsible for correctness of the statements provided in the manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right to reject submissions that do not meet the guidelines described in this section.

Images will be removed from publication if authors have not obtained informed consent or the paper may be removed and replaced with a notice explaining the reason for removal.

Research Data Policy

This journal operates a type 1 research data policy. The journal encourages authors, where possible and applicable, to deposit data that support the findings of their research in a public repository. Authors and editors who do not have a preferred repository should consult Springer Nature's list of repositories and research data policy.

List of Repositories

Research Data Policy

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Datasets that are assigned digital object identifiers (DOIs) by a data repository may be cited in the reference list. Data citations should include the minimum information recommended by DataCite: authors, title, publisher (repository name), identifier.

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If the journal that you're submitting to uses double-blind peer review and you are providing reviewers with access to your data (for example via a repository link, supplementary information or data on request), it is strongly suggested that the authorship in the data is also blinded. There are data repositories that can assist with this and/or will create a link to mask the authorship of your data.

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