Author’s response to reviews

Title: Anterior cruciate ligament reconstruction with quadriceps tendon-patellar bone allograft: matched case control study

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Author’s response to reviews:

<Reviewer 1 : Umile Giuseppe Longo>

MATERIALS AND METHODS

The study design is not immediately clear. Please start reporting that this is a retrospective study.

-> We rearranged the order of sentence from line 52 to 53 on page 3.

Report clearly inclusion and exclusion criteria, and how many patients were excluded based on each criteria. You should report the total number of ACL performed, independently from the graft.

-> We added a figure which showed the patient’s enroll process.

Patients lost to follow-up is not an exclusion criteria. The number of lost to follow-up should be included in the "case series" and that accounted in the "dropout rate"

-> We deleted ‘patients who lost to follow up’ in exclusion criteria.

One my biggest concerns is the process of graft choice. Since it is not a randomized study, how you discussed graft with patients? Since QT allograft has never been used, did how you suggested this to patients? Moreover, which is your first-choice graft?

-> We recommended QTPB autograft to the first choice of ACL graft. However, we recommended the QTPB allograft when patients had repulsion of donor site morbidity by harvesting autograft.
page 4 line 14: "screened" instead of "included"

-> We changed the word ‘included’ to ‘screened’.

page 4 line 37: When quadriceps tests were performed?

-> We added ‘at 6, 12 and 24 months’ at the end of the sentence.

page 4 line 49: add ethical committee approval number

-> We added ‘(No. H-1604-033-753)’ at the end of the sentence.

page 4 line 52: move the power analysis in the statistical subsection. The power analysis is moreover incomplete: which is your primary outcome in which the sample size is based?

-> The power analysis we performed was post-hoc analysis. In order to prevent the misunderstanding, we changed ‘the power analysis’ to ‘post-hoc analysis’. The ligament laxity checked by KT-2000 was primary outcome in which the sample size was based.

page 5 line 17: what does it mean "excised"? Is the bone block maintained attached to graft or not?

I would suggest you to add a foto of the prepared grafts (autograft and allograft)

-> Yes, the bone block attached to graft. And we added figures of prepared QTPB autograft and allograft.

page 6 line 1: which is the screws size?

-> We used the screw size 8mm diameter, 25mm length metal screw on femoral side and 10mm diameter, 25mm length screw on tibial side.

page 5 lines 13-33: please rephrase more schematically the rehab protocol because it is not clear.

-> We rephrased all sentences by the chronological sequence in a paragraph.

RESULTS

Please start reporting the follow up.

-> We added ‘An average follow-up time was 31.2 months.’ in line 121 to 122 on page 6.

page 7 line 8: this study has not a 2 years follow-up. it is more, therefore correct with "at final follow-up"
We changed ‘2 years follow-up’ to ‘final follow up’ in this paragraph.

Please add the number of patients stratified according to KT values (<3 mm, 3-5 mm >5 mm)

We added data on Table 2.

An important issue, is that according to the Lachman score you have 1 patients per group graded as II. According to most of criteria (see Crawford et al arthroscopy, and Grassi et al CORR 2017) these should be considered failures.

We mentioned about your comment in line 133-136, page 6.

What about ROM? you had arthrofibrosis of ROM loss?

Unfortunately, we didn’t check the exact value of the ROM. However, there were no complications like arthrofibrosis of knee joint. Therefore, we added ‘arthrofibrosis’ on line 144, page7.

DISCUSSION

page 8 line 8: the power recovery was not "much better". Please rephrase in less enthuastic form

We changed ‘much better’ to ‘relatively good’ in this sentence.

page 8 lines 18-20: delete since you aready repeated this sentence before

As your comment, we deleted the sentences in line 18-20, page8.

Please compare your data with other studies using quad autograft.

We checked other references and added a ‘Most clinical outcomes about ACL reconstruction with QTPB autograft in these studies were relatively good, which is also shown in our study.’ In line 158-159, page 7.

Discuss your failures

My biggest concern is the indications and clinical relevance: in which case you suggest this allograft? according most of big series and meta analysis and registries, allograft should be second-line choice in primary ACL. Probably revision would be an appealing situation to use (see Grassi et al BJJ 2017 meta analysis).

As we mentioned in discussion, quadriceps peak extension torque at 60° per second in the QTPB autograft group at postoperative 6 months was less than in the QTPB allograft group. Therefore, we could guess ACL reconstruction with QTPB allograft have advantage in patients who need early recovery; for example athletes. Then we added ‘Therefore, we could recommend
ACL reconstruction with QTPB allograft in patients who need early recovery; for example, athletes.’ in line 186-187, page 8.

And we added the contents that ACL reconstruction with allograft is an appealing situation on revision surgery in line 189, page 8 to line 192, page 9.

Moreover, limitations of this study are noticeable and should be discussed:

- lack of randomization (selection bias)

  We additionally explained our limitation about lack of randomization in line 193-196, page 9.

  (First, this study has a retrospective design and the patients were not assigned randomly, increasing selection bias. However, there were several strengths in this study, including the matched demographic features of these patients, same surgical techniques, fixation method and rehabilitation program, which increased the power of statistical results.)

- lack of MRI evaluation (signal intensity and graft maturation. this is important lack, since you don’t know the behavior of the graft intra-articularly, since this is the first time used. are you sure undergoes ligamentization similarly to other grafts?)

  We added this point by the third limitation in line 204-206, page 9. (‘Third, our study does not include MRI evaluation of reconstructed ACL to confirm the ligamentizations of ACL. However, we could make an assumption by clinical results including anterior drawer test, Lachman test, pivot shift test and a KT-2000 arthrometer.)

Most important: since this is short term, you should insist in the fact that this is a preliminary short term FU, and further study are needed to confirm the efficacy, since 2 years are few to see failures (please discuss this and report allograft in general failure rates -see maletis registry-)

  We added ‘Long-term follow up, randomized controlled study will be scheduled to confirm the efficacy of this study.’ in line 202-204, page 9.

REFERENCES: update with the above ref.

  We updated the reference you mentioned above.

TABLES

Use the median and InterQuartile Ranges for Tegner, and not the mean

  We changed the value for Tegner scale in table 3.
How you calculate KOOS? to my knowledge it is a 0-100 scale, with 6 subscales. Please explain in the methods, or correct.

-> We calculated KOOS by added all scores in 6 subscales. Therefore, minimum value of KOOS we calculated was 0 and maximum value of KOOS we calculated was 600.

I suggest to report the values of Qol, Sport, Pain, daily Activity, stiffness, symptoms subscales.

-> Unfortunately, this is the retrospective study. We didn’t record the values you mentioned above. In future, Long-term follow up, randomized controlled study will be scheduled about the same subject. At that time we reinforced the values.

FIGURE: add grafts photos, as suggested above

-> We added figures of prepared QTPB autograft and allograft(Figure 2).

<Joan Carlos Arles Monllau (Reviewer 2)>

ABSTRACT

The subsection of Conclusions should be identical to Conclusions in the text.

-> By accepting your comments, we standardized our conclusion in the discussion section and abstract section.

INTRODUCTION

Line 25. Although I agree that graft choice in anterior cruciate ligament (ACL) reconstruction is still controversial, this statement here is questionable, as some recent research showed exactly the opposite (23, Kane PW et al. Anterior cruciate ligament reconstruction with bone-patellar tendon-bone autograft versus allograft in skeletally mature patients aged 25 years or younger. Knee Surg Sports Traumatol Arthrosc 2016;24:3627-33).

-> By accepting your comment, we added ‘Although, some recent research showed ACL reconstruction with autograft leads to lower retear rates in younger individuals[1]’ in line 30-31 on page 3 and updated the reference.

METHODS

Line 12. This is a retrospective study and as such the number of subjects should be reported in Results.

-> We added ‘As we mentioned above, 45 patients in each groups were included in this retrospective study.’ at the beginning of the results.
Since 2012, it is recommended to follow the CONSORT guidelines when conducting a RCT. Do you do so?

- Unfortunately, this is the retrospective study. Therefore we did not conduct a RCT. However, if this article is published, we will research a RCT about same subject. At that time, we will follow the CONSORT guidelines.

How many surgeons were involved in the study (performance bias)? Or is it a single surgeon series?

- Two surgeons were involved in the study. However, both two surgeons were expert in arthroscopic surgery more than 10 years experiences.

Line 14. The reason to allocate the patients to either group is not clear.

- As the other reviewer’s request, we added a figure which showed the patient’s enroll process. Please check a figure 1.

According to what is said here it was based on patient or surgeon preferences and this introduces a possible selection bias. This is a limitation and an important point to clarify.

- We added a limitation about selection bias in line 193-196, page 9.

Line 45. In a series of more than 200 patients, supposedly of different BMI, it is surprising to see that all reconstructions have been performed with a graft of the same size.

With regards to the a priori calculation it has been recently stated that more than 100 patients were required in each arm to detect a difference for the majority of outcome measures, and over 800 to detect a difference in return to pre-injury activity level (Guo L et al. Anterior cruciate ligament reconstruction with bone- patellar tendon-bone graft: comparison of autograft, fresh-frozen allograft, and ð²-irradiated allograft. Arthroscopy 2012;28:211-7).

- In our experience, 10mm graft was available except the female patients who had short height. Fortunately, the female patients who had short height were not included in this study.

- According to your comment, we added our limitations that relatively small number of allograft group was included in this study.

RESULTS

How many patients were lost to follow-up?

- As the other reviewer’s request, we added a figure which showed the patient’s enroll process. Please check a figure 1.
A two-year minimum follow-up period may underestimate allograft failure.

-> Yes we agreed that point. Accordingly, we referred that point on the limitation of this study.

CONCLUSIONS

In line 48, I strongly believe that here you must include "at two years follow-up" at the end of this sentence.

-> We added ‘at two years follow-up’ at the end of sentence.

The last sentence, starting in line 50, although is a wise comment is not a conclusion you may draw from your work and as such it better fits in the Discussion section. In general this subsection should be identical to Abstract's Conclusions.

-> By accepting your comments, we standardized our conclusion in the discussion section and abstract section.

REFERENCES

Literature is up to date. However, I would recommend two more quotations: Kane et al. 2016 and Guo et al. 2012) as commented earlier on.

-> As your request, we updated our references.