Reviewer's report

Title: Acute Achilles tendon rupture: Minimally invasive surgery versus non operative treatment, with immediate full weight bearing. Design of a randomized controlled trial.

Version: 2 Date: 10 July 2007

Reviewer: Ching-Chuan Jiang

Reviewer's report:

General

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Summary
The protocol has been improved, but some important concerns should still be addressed.

Background
If the data about the minimally invasive surgical method is lacking, the authors should conduct a pilot study first. Especially, the surgeons need quite a learning curve to be familiar with the present surgical technique. The authors said that all the participants already had been using this protocol of the operative procedures (Intervention section). It means there should already be some experience. Why don’t you use the data from these patients?

Design of study
The operation procedure needs to be described in more detail. For example, how do the surgeons make drills on the calcaneus through a 5-cm skin incision so far away.

Design of collection data
The definition of the endpoints is still not clear enough, especially for the complications, the rate of which is the primary endpoint. For example, the definition of “Disturbed wound healing” is “Keloid formation or unusual scar formation”. This is not clear. The inter-individual variation may cause great biases, so are sural nerve injury, scar adhesion, etc. What are the criteria of the ultrasound findings for re-rupture? How to diagnose?

Why is re-rupture excluded from the complications? Re-rupture which is important for the eventual functional outcomes should be included in the primary endpoint.

Functional score should also be the primary endpoint.
Stratification of the patients seems necessary, because people with different occupations may have different functional demand.

Although this is an open label study, it is suggested that the evaluators had better be blinded about the treatment procedure.

Statistics

The authors emphasize the difference between the open method and minimally invasive surgical method. How can they still use the data of open method to calculate the sample size? It seems the difference of the complication rate may be small between minimally invasive method and conservative method. I believe the sample size of 72 must be underpowered. If this is not corrected, the present study will be substantially devaluated.

The statistical methods used for the endpoint comparison should be described, including the softwares.

One more point, the primary analysis of efficacy endpoints should be performed basing on the intent-to-treat (ITT) population. The dropouts and withdrawal have to be summarized and analyzed by treatment groups. A listing of subject with withdrawal, along with the date and reasons for termination should be provided. The last-observation-carried-forward (LOCF) procedure can be used to estimate the missing data for efficacy variables. No imputation should be done for estimating the missing values.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.