Author's response to reviews

Title: Augmentation Of Tibial Plateau Fractures With An Injectable Bone Substitute: CERAMENT™. Three year follow-up from a prospective study.

Authors:

Riccardo Iundusi (riccardo.iundusi@uniroma2.it)
Elena Gasbarra (elenagasbarra@tiscali.it)
Michele D'Arienzo (mdarienzo@unipa.it)
Andrea Piccioli (piccioli.and@gmail.com)
Umberto Tarantino (umberto.tarantino@uniroma2.it)

Version: 4
Date: 29 March 2015

Author's response to reviews: see over
Dear Editor,

thank you for your consideration of our manuscript for publication.

We have reviewed the above manuscript as suggested in your reviewer’s comments.

Reviewer # 1 (Dr. Stefano Campi)

Minor Essential Revisions

1. Line 71: “weight bear” should be changed to “weight bearing”.
   Change made as indicated by the reviewer.

2. Line 81-102: I suggest to move this section to the discussion paragraph. The introduction is long enough.
   This section has been moved to the discussion paragraph, as indicated by the reviewer, before the sentence "It can be concluded from our preliminary review that radiological and clinical outcome was satisfactorily obtained in all cases without complications.".

   The sentence "Simpson and Keating [14] in their clinical series of 26 patients concluded a less than 1 mm mean residual plateau depression at a minimum one year follow-up with the use of a calcium phosphate based bone cement versus bone grafting (approximately 4 mm)." at line 175-178 was deleted. Line 178-180 "They also were able to use less hardware with the calcium phosphate group and had a corresponding 40 percent reduction in operative time on average (from a mean of 101 minutes to 55 minutes)." has been located at the end of the moved section but before the sentence " Larsson and Hammick [19] in their analysis of randomized clinical trauma studies support the benefits of injectable calcium phosphate based bone substitutes as suitable alternatives to autograft, with the flexibility to be applied around the hardware once in position and to augment weaker bone around the screws as well as replace autograft in defects and voids".
Of course, all involved individual reference number in square brackets, in the order in which they are cited in the text, have been modified as the References paragraph.

3. Line 90: the word “fracture” is missing.
   "fracture" added as suggested by the reviewer.

4. Line 156: “The time course of resorption of CERAMENT and remodeling to new bone was assessed via radiographic analysis...” I suggest to report here the X-ray findings (i.e. “the CERAMENT resorption was complete in all cases after X months”...or after X months in X patients, Y months in Y patients...or anything else the Authors have found)
   
   We have now changed this sentence as suggested by the reviewer in "The CERAMENT resorption was complete in all cases after an average of 5 months (3 to 8 months)." and moved it after the sentence "Radiographic analysis demonstrated that a loss of fracture reduction was maintained within the satisfactory range of 2 mm, with an average of 1.18 mm as presented in Table 2." and before of the previous "Rasmussen knee function score was 26.5, with fourteen patients exhibiting an excellent result and the remaining ten with a good rating." After this last sentence we added "A case of a 35 year old female with a Schatzker II, Müller AO grade 41-B3 fracture, is presented in Figure 1, 2, and 3." also to comply the next minor revision.

5. Line 157-164: I suggest using this paragraph as figure legend for figures 1, 2 and 3.
   Change made as indicated by the reviewer.

6. Discussion: The strength of the paper could be improved by adding the limitations and strengths of the study in this section. (i.e. One surgeon/different surgeons, control group, different type of fractures included, etc).
   
   The sentence "This investigation has some limitations. The study population is relatively small and doesn't effectively represent all types of tibial plateau fractures. Three out of the authors performed the surgical procedures. Next, a control group using other bone substitutes or grafting was not enrolled. Lastly, patients were followed for a mid-period, so further studies will be required to verify the long-term clinical and radiological outcomes." has been added at the end of Discussion as suggested by the reviewer.

Reviewer # 1 (Dr. Vincenzo Giordano)

Major Compulsory Revisions

1. I'd like to suggest to the authors to better identify their patients, mainly using also the Schatzker classification. According to the AO classification, B type fractures are unicondylar and can involve both the lateral and the medial tibial condyles. However there is a huge difference between performing an
indirect reduction and percutaneous fixation between both sides and therefor in general the majority of the orthopaedic surgeons prefer to perform an ORIF for medial condyle fractures. I feel this clarification in necessary for better illustrate the technique

Schatzker classification was mainly used as suggested by the reviewer. The sentence "The Müller classifications were used and was type B2 in 12 patients, B3 in 7 patients, C1 in 2 patient and C3 in 3 patients." at line 47-49 was changed in "Both Schatzker and Müller classifications were used and was type II or 41-B3 in 7 patients, type III or 41-B2 in 12 patients, type IV or 41-C1 in 2 patient and type VI or 41-C3 in 3 patients, respectively." A part of the period "with Müller AO classifications of B1 to B3 and C1 to C3 and" which was at line 89-90 was deleted.

The sentence "Progressive load bearing was allowed after 2 weeks for Müller AO type B fractures and after 4 weeks for type C fractures." which was at line 136-137 was changed in "Progressive load bearing was allowed after 2 weeks for Schatzker II and III or Müller AO type 41-B fractures and after 4 weeks for type IV and VI or type 41-C fractures."

The sentence "A CT scan was taken preoperatively to examine the fracture, for surgery planning and for fracture classification according to Müller [18]." which was at line 142-143 was changed in "A CT scan was taken preoperatively to examine the fracture, for surgery planning and for fracture classifications according to Schatzker [10] and Müller [11]."

The sentence "Schatzker classifications were type II (7 patients), type III (12 patients), type IV (2 patients) and type VI (3 patients);" was added at the beginning of the period in the RESULTS which was at line 147.

The sentence " Müller classifications were as follows: B2 (12 patients), B3 (7 patients), C1 (2 patient) and C3 (3 patients)." which was at line 147 was changed in " Müller classifications were as follows: 41-B2 (12 patients), 41-B3 (7 patients), 41-C1 (2 patient) and 41-C3 (3 patients)."


"Schatzker Classification N=7  II;  N=12  III;  N=2  IV;  N=3  VI" was added in Table 1.

In Table 2 we added:

<table>
<thead>
<tr>
<th>Schatzker Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=4  II;  N=12  III</td>
</tr>
</tbody>
</table>
2. If many procedures were performed via an open approach, why to do a medial window to use the bone substitute instead of doing that directly by the lateral window? I think the authors should also clarify this particular step in their technique.

We clarified our technique as indicated by the reviewer: in the RESULTS, the sentence "Fifteen patients were operated with two cannulated screws and the remaining six patients needed an angled stable sliding plate with screws." which was at line 148-149 was changed in "Fifteen patients (all type II or 41-B3 and 8 patients out of type III or 41-B2) were operated with two percutaneous cannulated screws which were inserted through the lateral side after that a distal medial window to reduce the fracture first, and to introduce the bone substitute later, was performed; the remaining nine patients (4 patients out of type III or 41-B2, all type IV or 41-C1 and all type VI or 41-C3) needed an angled stable sliding plate with screws and the bone substitute was inserted directly by the lateral approach."; also the METHODS were improved with the sentence "(all patients of Schatzker type II or Müller 41-B3 and 8 patients out of type III or 41-B2)" added after the word "reduction" which was at line 127.

Minor Essential Revisions

1. I think there is much information than it is necessary about the CERAMENT during the METHODS description. Authors should refer to some specific literature about the bone filler instead of describing in a large paragraph the material.

CERAMENT platform is a pretty new bone substitute family with only few indexed articles referring CERAMENT SPINE SUPPORT but no literature describes the CERAMENT BONE VOID FILLER which is quite different; our paper is the first paper which could be published describing this new bone substitute (CERAMENT BONE VOID FILLER) so we would prefer to describe the material as we did in this manuscript.

2. At the beginning of the METHODS the authors cited that their patients ranged from 18 to 70 years old, then at the RESULTS section they cited that their patients ranged from 32 to 64 years old. I understood that during a 12-month period they treated more than the 24 patients from the study at
their institution, but I think it should be interesting to show the exact number of admissions at their institution during the period of the study.

Data improved as suggested by the reviewer.

The sentence "A total of 24 patients, 12 males and 12 females, were included over the 12 month recruitment period and were treated by three of the authors." which was at line 145 at the beginning of the RESULTS, was changed in "Ninety-three consecutive patients with a tibial plateau fracture presented at the Emergency Department of the University Hospital "Tor Vergata" over the 12 month recruitment period. A total of 24 patients, 12 males and 12 females, met the inclusion criteria and were included and treated by three of the authors:".