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KNEE REVISION SURGERY

Use of porous custom-made cones for meta-diaphyseal bone defects reconstruction in knee revision surgery: a clinical and biomechanical analysis

Giorgio Burastero[1] · Silvia Pianigiani[2] · Cristiana Zanvettor[3] · Luca Cavagnaro[1] · Francesco Chiarlone[1] · Bernardo Innocenti[3]

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Abstract

Introduction Although the practice of metaphyseal reconstruction has obtained successful clinical and radiological results in revision total knee surgery, off-the-shelf devices aren't an effective solution for all patients as they do not cover the full range of clinical possibilities. For this reason, during severe knee revisions, custom-made porous titanium cementless metaphyseal cones are nowadays employed as alternative to traditional surgeries. The aim of this study is to understand the benefits gained by the use of the custom-made cones against the performance of more traditional techniques, such as the use of cemented or cementless stems. Thus, a retrospective study on eleven patients and a biomechanical finite element analysis (FEA) was developed, based upon three clinical cases of the clinical analyzed cohort.

Materials and methods Eleven patients underwent staged total knee arthroplasty revision with the use of 16 custom-made cones to correct severe femoral and tibial meta-diaphyseal bone defects. Clinical scores and range of movement were observed during the follow-up period (mean follow-up 26 ± 9.4 months). Reason for surgery was periprosthetic joint infection (PJI) in eight patients and post-traumatic osteomyelitis in the other three patients. Three patients previously affected by PJI were selected among the eleven patients of the clinical population. For those patients, bone geometries and implants during surgery were replicated in silico and analyzed during different daily activities. For the same patients, as alternative solution for surgery, the use of cemented or cementless stems was also simulated by FEA. Stress patterns in different region of interest and risk of fracture in the bone were calculated and compared.

Results No loosening, component migration, or mismatches between preoperative planning and intraoperative findings were clinically registered. Biomechanical results demonstrated that the use of custom-made cones induces a more homogeneously distributed bone stress than the other two techniques that concentrate the stress in spotted regions. The risk of fracture is comparable between the use of custom-made cones and cemented technique, while press-fit configurations increase the risk of fracture (more than 35%).

Conclusions Based upon the clinical evidence and the findings after the FEAs, the practice of porous custom-made metaphyseal cones in severe revisions of knee arthroplasties is showing promising biomechanical results. The homogeneous stresses distributions and the lower bone stress gradient could justify a reduction of bone fractures and the risk of implant loosening which could be the explanation to the successful clinical outcomes.

Keywords Revision TKA · Bone stress · Custom-made cone · Stem · Severe bone defect · Clinical analysis

Introduction

Revision total knee arthroplasty is one of the most challenging procedures in orthopedic surgery. Since 2003, the number of total knee arthroplasty (TKA) in the United States has increased by 130%, and the number is expected to increase worldwide [1]. Revision TKAs are estimated to increase accordingly [2–7]. The main reasons for knee revisions

✉ Bernardo Innocenti
bernardo.innocenti@ulb.be

Extended author information available on the last page of the article

are aseptic loosening, periprosthetic joint infection (PJI), periprosthetic fractures, major osteolysis, extensor mechanism problems, instability, and stiffness [8, 9].

Several issues could jeopardize the final outcome in terms of restoration of knee biomechanics, bone loss management, and durable implant fixation. Bone defects restoration, especially in the metaphyseal region, is one of the key-point for a stable and durable prosthesis. The "Anderson Orthopaedic Research Institute" (AORI) classification is commonly used to describe around-the-knee bone loss in revision TKA [10]. In detail, Type I has minor cancellous bone defects which will not jeopardize the stability of the prosthetic component. Metaphyseal cancellous bone loss with damaged cortical bone frame a type II defect. Type IIA involves one condyle or hemi-plateau. In Type IIB, bone loss involves both femoral condyles and/or the entire tibial plateau. Type III is a major deficiency in metaphyseal bone, extended to both femoral condyles or both sides of the tibial plateau and tibial tuberosity. Type II and III defects can be classified as major bone loss. Classified minor bone defects (smaller than 5 mm) should be managed with cement and morselized bone graft for optimal outcomes [11–13]. On the other hand, more severe bone loss management (types II and III) [11] have not consensus on how they should be treated. While cement reinforced with screws or the use of modular augments have shown optimal mid-term clinical results for type IIA [14–16], for type IIB or type III possible solutions are available, such as structural allografts, porous cones, sleeves or wide bone resection with mega prosthesis implantation [17–20]; however, no common agreement among clinician exist on which is the optimal solution.

When surgeons need to treat severe bone loss, off-the shelf devices such as augments, porous metal cones or sleeves are possible solutions. Indeed, these techniques have shown optimal clinical and radiological results with relatively low complication rates [21, 22]. Nevertheless, in case of massive meta-diaphyseal bone loss these systems do not provide a safe and reliable fixation to the prosthetic components. In such clinical settings, an innovative method to treat metaphyseal bone loss in revision knee prosthesis consists in the use of custom-made porous metaphyseal cones [1]. In particular, the cones are tailored to the patient's anatomy to reconstruct the effective lost bone morphologies and mechanical structure.

So far, the practice of porous custom-made cones has obtained successful clinical and radiological early term results [23–26]. Nevertheless, the literature is still lacking in the understanding of the biomechanical effects of such personalized technique.

The aim of this study is dual, a clinical retrospective study and a biomechanically analysis to develop a comparative finite element analysis of the use of custom-made cone versus traditional surgical techniques during sever revision TKAs. In detail, three accomplished surgeries are selected among eleven patients of a retrospective study who received custom-made porous titanium cementless metaphyseal cones. For those selected patients, bone geometries and the same custom-made implant used to cover the defects during the severe revision TKA were reconstructed and virtually implanted as during surgery.

For the three patients, two presented both a tibial and femoral custom-made cones, while one patient had only the femoral custom-made cone. All observed cones are different from each other as designed on the bone morphology of the patient. Thus, three different models were made, one for each analyzed patient. Every model differs from the others, as the bone geometries were patient-specific, the cone was customized and the TKA implant and stems were defined according the patients' dimensions.

To verify and understand the benefits of such custom-made cones, for the same three analyzed patients, the use of cemented stems and the use of press-fit stems as traditional techniques were simulated as well during a biomechanical finite element analysis (FEA). As reported in the literature, FEA can be considered a robust support for such kind of analyses [27, 28].

The novelty of this study concerns an investigation for solutions used during severe knee revisions both from a clinical and a biomechanical point of view. The retrospective clinical study was performed on eleven patients. Patients belonging to that cohort were all affected by distal femoral and/or proximal tibial bone losses so severe to make the use of multiple off the shelf cones to stabilize the implant not advisable.

The comparison among the traditional techniques and the use custom-made porous titanium cementless metaphyseal cones through the results obtained by the FEAs allows to draw clinical and biomechanical evidences that could be useful to help in planning severe knee revisions for which achieving joint restoration and patient's satisfaction is challenging.

Materials and methods

Clinical study

In the period 2015–2019, the same surgeon performed 11 staged knee revisions (Fig. 1) implanting 16 porous titanium custom-made meta-diaphyseal cones. Every patient gave his/her written informed consent to have his/her clinical records later used for this study. The custom-made devices were combined with a hinged prosthesis in nine cases and with a constrained condylar implant in two patients. All prosthetic components were provided by the same manufacturer (Zimmer-Biomet, Warsaw, IN). No patellar resurfacing was

Fig. 1 Intraoperative view of a wide meta-diaphyseal tibial bone defect after complete debridement

performed. Among the 11 patients, 8 (72.7%) were males and 3 (27.3%) were females. Mean age at re-implantation was 63.7 ± 10.0 years. Five (45.5%) revisions were performed on the left side. Reason for the surgery was PJI in eight patients (72.7%) and post-traumatic osteomyelitis in the other three patients (27.3%). Mean number of previous surgeries on the affected knee was 4.8 ± 2.0. In details, Table 1 summarizes the main features of the treated patients. The mean follow-up was 27.1 ± 14.4 months. Clinical and radiographic evaluations were performed at 45 days, 3, 6, 12 months after surgery and annually thereafter. Standing AP, lateral, and merchant radiographs were evaluated according to the system of the Knee Society for bone cement interface radiolucency. Osseointegration, polyethylene wear, prosthetic components migration, alignment and osteolysis were evaluated. Every possible complication related to the operated knee was recorded.

The Knee Society score (KSS), the Oxford Knee score (OKS) and visual analogue scale (VAS) for pain evaluation was calculated pre-operatively for all patients and also at scheduled follow-up. The active range of motion was determined with the use of a standard clinical goniometer.

Among the 11 treated patients, 3 patients (named case 1, 2 and 4 of Table 1) with at least 2 years of follow-up were selected for the biomechanical investigation (Fig. 2).

Table 1 Demographic and clinical data of the cohort

Case #	Gender	Age	Side	Bone defect (AORI)	Reason for treatment	Number of previous surgeries	Side of custom-made device	Final implant	Complications	Final follow-up (months)
1	F	71	L	F3–T3	PJI	4	Femur-Tibia	RHK	No	50
2	F	66	L	F3–T3	PJI	5	Femur-Tibia	RHK	No	45
3	M	58	R	F3–T3	PJI	3	Femur	RHK	No	40
4	M	66	R	F3–T3	PJI	5	Femur	RHK	No	38
5	M	56	L	F3–T2B	PJI	10	Femur	RHK	No	28
6	M	65	R	F2B–T3	Post-traumatic OM	3	Tibia	CCK	Septic recurrency	6
7	M	62	R	F3–T3	PJI	5	Femur-Tibia	RHK	No	24
8	M	82	R	F3–T3	PJI	5	Femur-Tibia	RHK	No	22
9	M	49	L	F2A–T3	Post-traumatic OM	3	Tibia	CCK	No	19
10	F	51	L	F2A–T3	Post-traumatic OM	4	Tibia	RHK	No	14
11	M	75	R	F2B–T3	PJI	6	Tibia	RHK	No	12

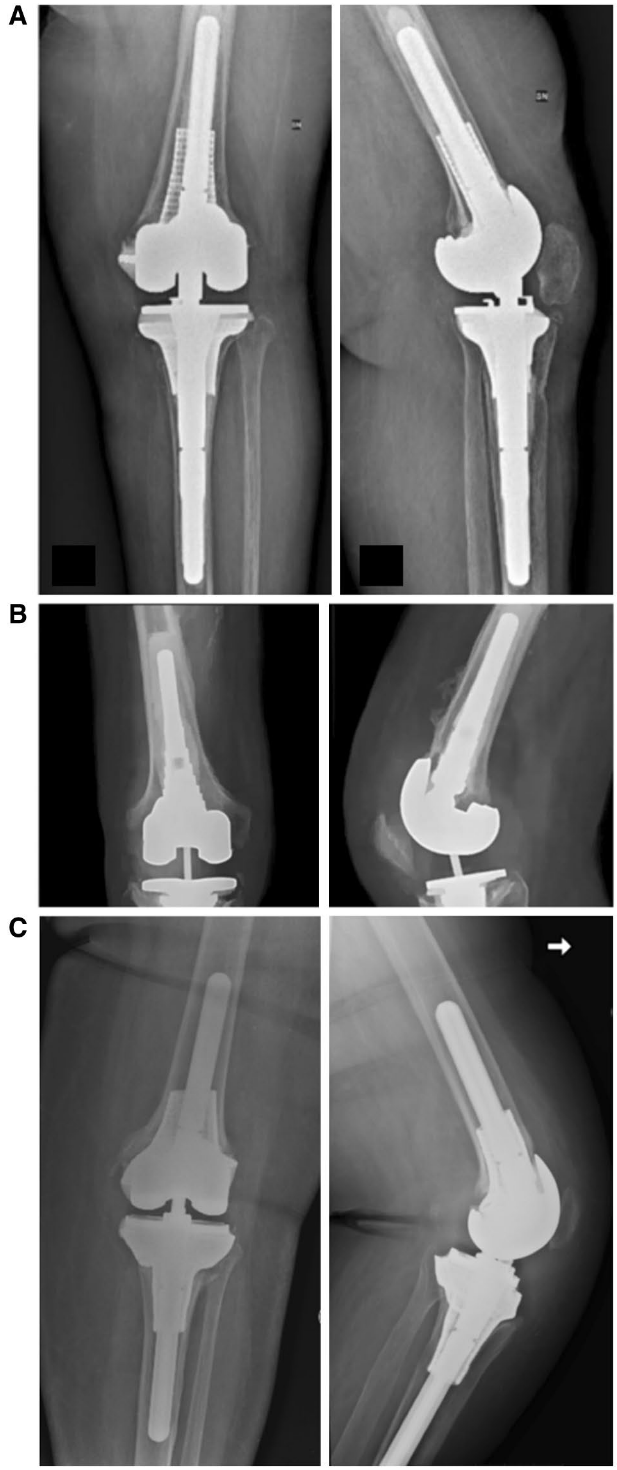

Fig. 2 Final follow-up X-rays of the three analyzed cases: **a** case 1, **b** case 2, **c** case 3. In case 2 only the femoral bone is shown as only the femoral cone was used

Case 1 (Fig. 2a):

The first case is a 71-years-old woman with left knee pain unrelated to mechanical activities. She underwent a TKA for knee osteoarthritis in 2011. The patient complained persistent pain and swelling immediately after surgery with subsequent formation of fistula and purulent drainage. In 2012, a DAIR procedure (debridement, antibiotics and implant retention) was performed and the patient started an empiric antibiotic therapy. After 6 months a second debridement was attempted. The patient was referred to our department with progressive knee pain and heavy limitation of daily life activities. Little ambulation was possible with the help of crutches and a fistula was present. C-reactive protein (CRP 72 mg/L) and erythrocyte sedimentation rate (ESR 95 mm/h) were persistently elevated. Radiological analysis showed a revision prosthesis with stemmed component of the tibia side and progressive osteolysis on both femoral and tibial metaphysis. Intraoperative microbiological analysis demonstrated a polimicrobic infection sustained by Staphylococcus capitis and Corynebacterium amycolatum.

Case 2 (Fig. 2b):

The second case is a 66-years-old obese woman with progressive left knee pain. The patient reported an arthroscopic surgery for medial meniscectomy in 1994. Left TKA was performed in 2010. One year later, she was diagnosed with a PJI and underwent a two-stage revision protocol. On physical examination, her knee showed a partially retracted scar with fistula and purulent drainage. Swelling and inflammation signs were present. Her limb alignment was neutral. The range of movement was limited from $-5°$ to 30° and pain was accused along the motion. A concomitant drug-induced (Linezolid) peripheral neuropathy was reported. Radiographic analysis performed at the time of our first evaluation showed a knee revision prosthesis with press-fit tibial and femoral stems. Metaphyseal tibial and femoral osteolysis consistent with AORI type III defects were observed. Serologic tests showed high levels of CRP (96 mg/L) and ESR (130 mm/h). No arthrocentesis was performed. Methicillin–susceptible *Staphylococcus epidermidis* (MSSE) was obtained from intraoperative tissue samples microbiological analysis.

Case 3 (Fig. 2c):

The third case was a 66-years-old male with chronic right knee PJI. The patients suffered from a complex right tibial fracture with subsequent malunion (1995) and was affected by cardiopathy and hypothyroidism. In 2008, he underwent a TKA for knee osteoarthritis followed by a two-stage revision in 2010. In November 2011, septic failure was diagnosed and managed with arthroscopic washing and suppressive therapy. He came to our attention in 2015 with highly retracted midline scar, draining fistula and no possibility of ambulation on the right leg. Radiological investigation revealed a revision total knee prosthesis with metadiaphyseal bone loss both on tibial and femoral side. Intraoperative microbiological data showed Methicillin-resistant *Staphylococcus epidermidis* (MRSE).

Biomechanical study

Analyzed cases for biomechanical analysis

For the biomechanical analysis, the three selected cases were analyzed.

Revision surgical techniques

Since the aim of the study is the evaluation of the potential benefits of the use of custom-made cones during severe knee revision in comparison with two alternative common techniques, three accomplished surgeries were numerically analysed and modelled. In the developed models, patella is not geometrically considered, but its contributions are included in the boundary conditions, as reported in the literature [29–31]. To understand the effects on the same patient when using customized or traditional techniques, the changes in bone stresses and the risk of fracture are observed. To understand the effects on the same patient when using customized or traditional techniques, the changes in bone stresses and the risk of fracture are observed.

The three compared revision knee techniques are:

- Technique A: use of porous titanium custom-made metaphyseal cones and stems thinner than the diaphyseal canals;
- Technique B: use of cemented stems;
- Technique C: use of press-fit stems.

Simulated daily activities

For all patients and replicated surgeries, three different configurations were considered (Fig. 3):

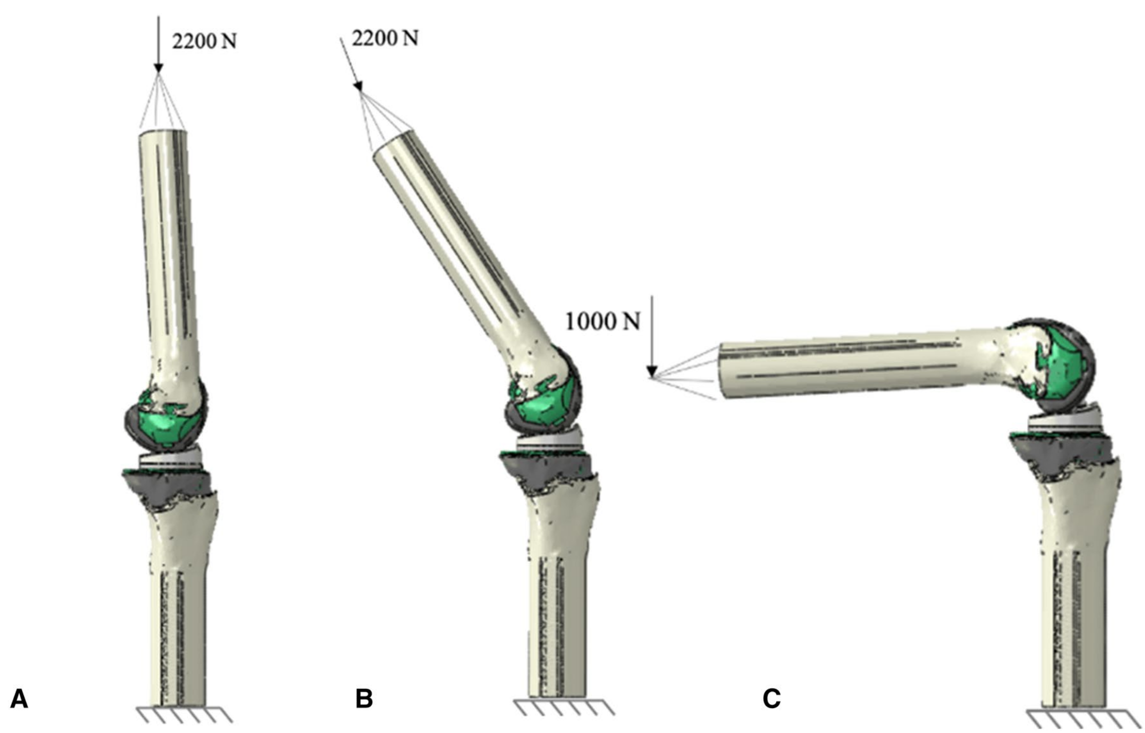

Fig. 3 Forces and constraints applied for the three analyzed configurations: **a** full-extension, **b** gait, **c** chair-rise

Full-extension (0° of flexion): replicates the standing position. The tibia is distally fixed and an axial load (cranio-caudal direction) of 2200 N is applied on the proximal surface of the femur (Fig. 3a).
Gait (30° of flexion): replicates the flexion at the maximum angle in the stance phase of gait, that also coincide with the highest force during walking. The tibia is distally fixed and a load of 2200 N is applied on the proximal surface of the femur with an inclination of 15° with respect to the longitudinal axis (Fig. 3b).

These two previous conditions replicated the maximal knee axial force during gait corresponding to about 3.1 times of 70 kg body weight as already implemented in previous studies [13, 32–34].

Chair-rise (90° of flexion): investigates the getting up from the sitting position. The tibia is distally fixed and a load of 1000 N is applied on the proximal surface of the femur in the cranio-caudal direction. The magnitude of the force is reduced with respect to the other configurations as, usually, hand support is used during getting up from sitting position (Fig. 3c).

All applied loads were in agreement with previous study in the literature [28, 29, 30, 35–38].

Geometries and properties

The same total knee replacement was used for all patients. The CAD files of the custom-made metaphyseal cones were provided by Adler Ortho (Cormano, Milano, Italy). The custom-made cones were based on computed tomography (CT) scans and tailored on patient's specific anatomy. The aim was to provide adequate fixation to the prosthetic components and restore patient's anatomy and knee biomechanics using the contralateral unaffected knee as reference configuration. Thus, the cones are designed to precisely fit inside the remaining patient's bone and to host the prosthesis implants.

The posterior-stabilized femoral component is made of Chromium Cobalt Molybdenum alloy (CoCrMo ISO 5832). The tibial inserts are made of ultra high molecular weight polyethylene (UHMWPE). The tibial component is made of titanium aluminum vanadium alloy (Ti6Al-4V Gr.5 ISO 5832-3). The femoral and tibial stems are made of titanium aluminum vanadium alloy Ti6Al-4V Gr.5. The stems used

Table 2 Material properties and models used for the study

Material	Material model	Young's modulus [MPa]	Poisson's ratio
Cortical bone	Transversely Isotropic	$E_1 = 11{,}500$	$\nu_{12} = 0.58$
		$E_2 = 11{,}500$	$\nu_{13} = 0.31$
		$E_3 = 17{,}000$	$\nu_{23} = 0.31$
Cancellous bone	Elastic isotropic	2,130	0.31
CoCrMo	Elastic isotropic	2,10,000	0.29
Ti6Al4V	Elastic isotropic	1,20,000	0.30
Ti-porous	Elastic isotropic	25,000	0.35
PMMA	Elastic isotropic	300	0.35

For the cortical bone, the direction E3 represents the axial direction

Fig. 4 Example of design of the custom-made femoral and tibial cones (in the figure is reported the one related to patient 1)

in the models of the technique A have the same geometry of those used during surgery, while the stems for the technique B and C were adapted for replicating cemented or press-fit techniques. The custom-made metaphyseal cones are made of porous titanium (Fig. 4). According to the literature [13, 29, 31, 34], all materials used in the models are considered homogeneous, linear elastic isotropic with exception of the cortical bone that is considered linear transversely isotropic (with principal axis the mechanical axis of the bone), the main properties are reported in Table 2. For the simulations, all contact pairs are considered fully bonded with the exception of friction between femoral component and insert, custom-made cone and femoral or tibial component, and cement and stem ($\mu = 0.2$) [28].

Mesh and outputs

All the parts were analyzed using finite element analysis using a linear tetrahedral mesh with elements sizes chosen accordingly to the interested part. A proper convergence analysis was performed to assure proper mesh quality [27]. Stress contours and quantitative values on bones and on the implant stem were analyzed for the three patients under the different loading conditions.

To establish the potential for femoral bone fracture in the different loading conditions, a risk for fracture (RF) was therefore calculated. According to the literature [39, 40], RF was defined as the ratio between the maximum principal strain in the femoral or in the tibial shafts (either compressive or tensile) and the corresponding ultimate strain limit [40]:

$$\mathrm{RF} = \varepsilon_{\max} / \varepsilon_{\lim},$$

where $\varepsilon_{\max}$ is the maximum principal strain in the bone shaft; $\varepsilon_{\lim}$ is the ultimate strain limit. The ultimate strains limit for bone are different for compressive and tensile conditions; in details, for compression the $\varepsilon_{\text{lim-compressive}} = 0.0104$, while for tension the ultimate tensile strain limit was taken as 70% of the previous value ($\varepsilon_{\text{lim-tensile}} = 0.0073$) [40].

All simulations were performed with Abaqus version 6.14–5 (Dassault Systemes, Velizy-Villacoublay, France).

Results

Clinical results

All custom-made cones appeared well osseointegrated and the radiographic analysis showed no evidence of custom implants loosening or migration at a mean follow up of 26 ± 9.4 months. Up to now, we reported one septic failure managed with above-the-knee amputation. No implant mismatch between the preoperative planning and the final implant was reported. Specifically, the first patient reported a KSS of 84, a OKS of 41 and a VAS of 2 at final follow-up. The active range of motion was from 90° of flexion to full extension. The second patient analysed reached a KSS of 90, a OKS of 43 and a VAS of 2. The active flexion was 95° up to complete extension and no extension lag was found. KKS, OKS and VAS of the third patient were 84, 38 and 3, respectively. Range of motion was 0°–90°. The three patients walked without crutches and fully recovered their daily life activities.

Biomechanical results

Generally, patients 1 and 3 presents more similar results with respect to patient 2. The following results can be justified by the fact that patient 2 only presented the implant in femoral compartment and the remaining femoral bone was in conditions more severe than the other two patients. Figure 5 shows the qualitative trends for the three patients for the full-extension configuration. Generally, observing the loaded full-extension, Technique A better distributes the stress generating a homogenous stress contour on both bones while the other two techniques concentrate the stress on spotted regions. The discontinuous stress distribution can bring to local peaks of stress that could generate bone fractures.

Figure 6 shows the qualitative trends for the three patients for the gait configuration. Figure 7 shows the qualitative trends for the three patients for the chair standing up configuration. As observed for the full extension, for the other two simulated daily tasks, the use of a custom-made cone induces a more homogeneous stress distribution as well.

Tables 3 and 4 reported the maximum and the average von Mises stress in the stem for the different techniques among the three patients for femur and for the tibia (in this case only patient 1 and patient 3 are considered). For all the three patients, the use of a press-fit technique induced an increase in the stress surrounding the stem, in comparison with the other two techniques. The increase is mainly marked in the femoral stem.

Figures 8 and 9 illustrated the average and the maximum von Mises Stress calculated as mean value among the three patients for femur and for the tibia stem (in this case only patient 1 and patient 3 are considered). Analyzing separately the three daily tasks, the results clearly demonstrate that the use of custom-made cones (Technique A) always induces a lower stem stress compared to the other two techniques.

To quantify the eventual bone overload induced by the different techniques, the risk of fracture [39, 40] was also determined calculating the strain for every patient during all daily activities and it is reported in Fig. 10 for every combination of technique and daily task among patients; in

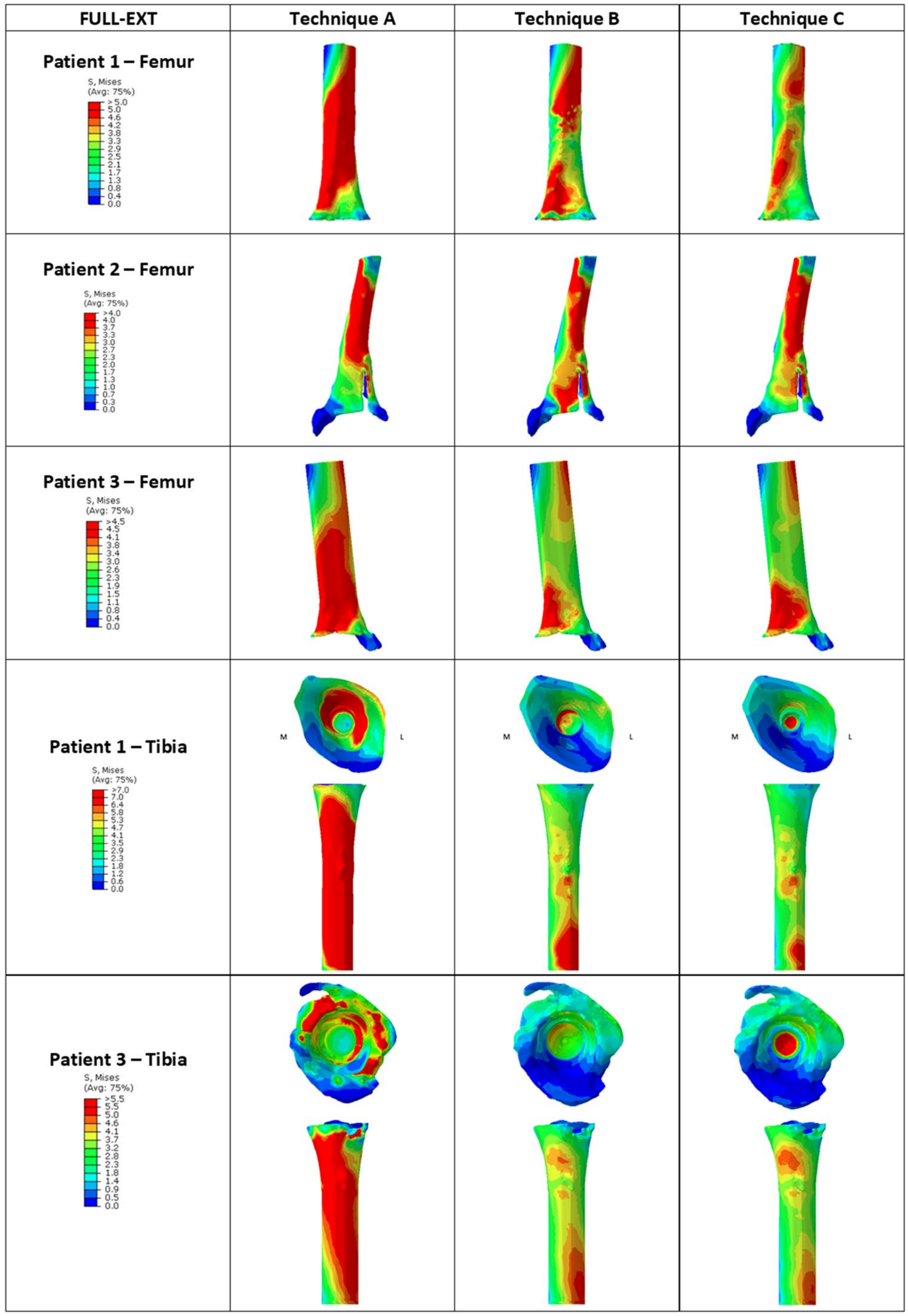

Fig. 5 Graphical overview of the von Mises stress for the three patients for the full-extension configuration. Each column represents the values for each technique analyzed, while, the rows indicate the different patients modelled

details a 100% (or greater) value indicates fracture, while lower values indicate lower chance of fracture.

In general, the use of cement (technique B) confirms the literature study results in preventing the risk of bone fracture [28] with the lowest reported values, both on the tibial and femoral bone, among the investigated configurations; technique A has very similar findings, while technique C (press-fit stem) reported the highest risk of fracture, in agreement with other biomechanical studies [29, 41].

Discussion

Massive bone defects management is one of the major challenge in knee revision surgery [42]. Custom-made cones are a new and promising option in this surgical setting.

Our group firstly reported the experience with such devices showing optimal short-term clinical and radiological outcomes [1, 21, 22] for patients belonging to that cohort were all affected by distal femoral and/or proximal tibial

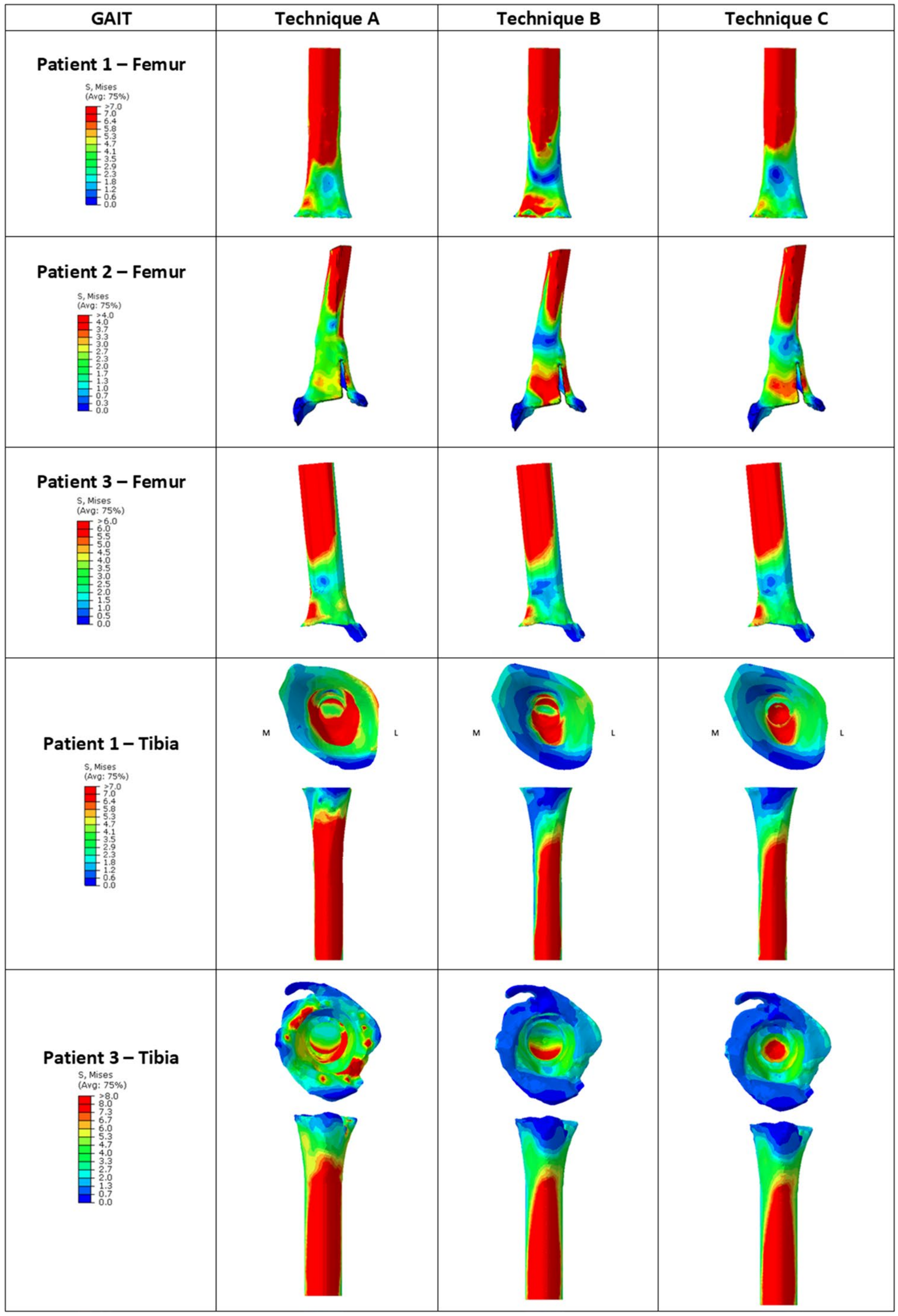

Fig. 6 Graphical overview of the von Mises stress for the three patients for the Chair-rise configuration. Each column represents the values for each technique analyzed, while, the rows indicate the different patients modelled

bone losses so severe to make the use of multiple off the shelf cones to stabilize the implant not advisable. These results are confirmed by Cherny et al. [23]. The authors reported promising short-term clinical data on 30 patient-specific titanium cones with no radiological or clinical complications.

Usually, prosthetic knee revision stability relies on strong fixation of components according to the "zonal fixation" concept postulated by Morgan-Jones [43]. The authors agree that good fixation should be achieved in at least 2 zones [42]. Custom-made porous metal cones provide reliable stability in the meta-diaphyseal region involving a "novel" zone of implant fixation halfway a pure metaphyseal zone and a pure diaphyseal one. As a consequence, custom devices should be considered as an intermediate option between standard "off the shelf" metaphyseal fixation tools and massive bone resection with megaprosthesis implantation. In light of the successful

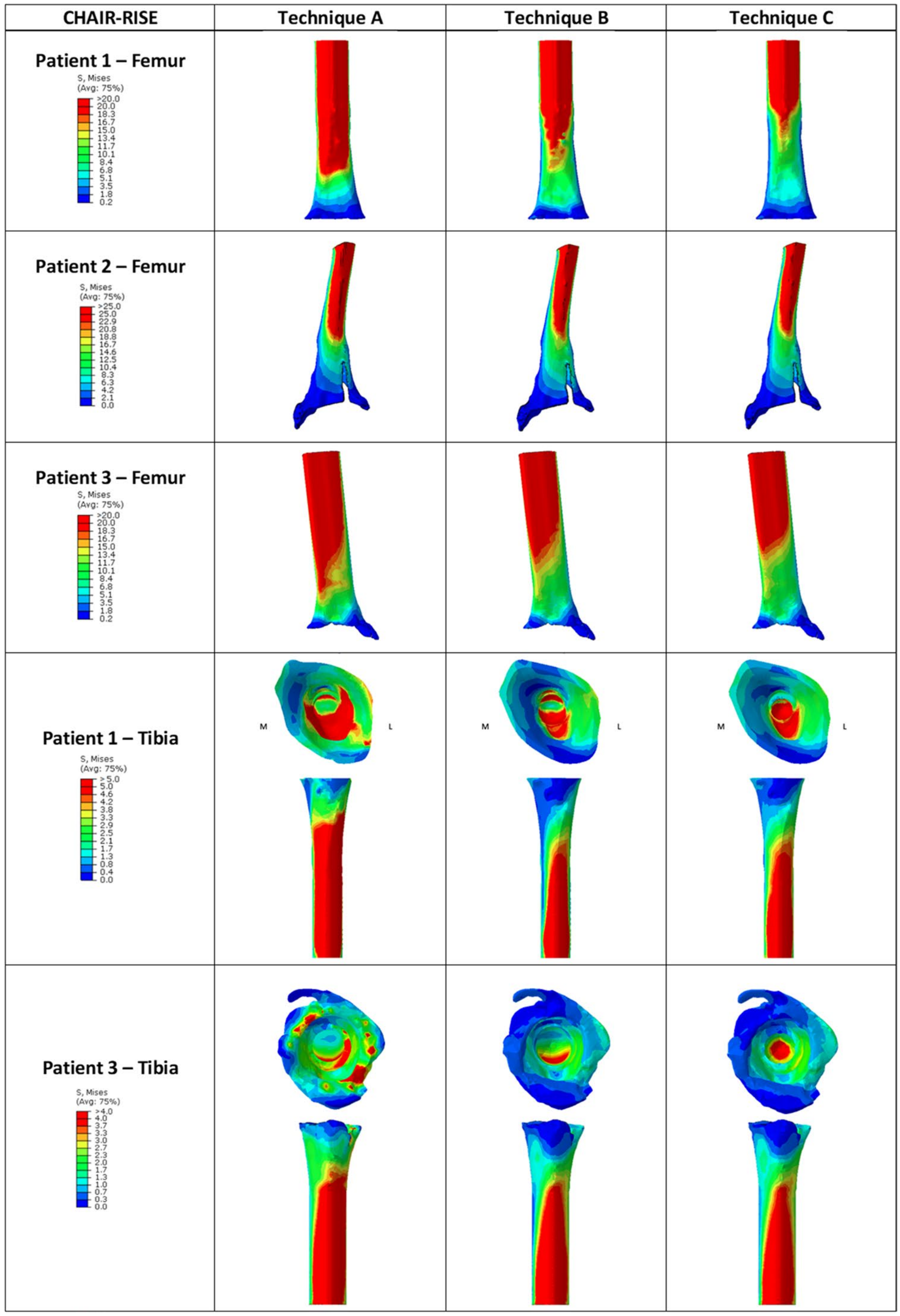

Fig. 7 Graphical overview of the von Mises stress for the three patients for the gait configuration. Each column represents the values for each technique analyzed, while, the rows indicate the different patients modelled

clinical results, a biomechanical explanation was lacking in the literature for the understanding of the effects once custom-made meta-diaphyseal cones are used in sever revisions of knee arthroplasty.

This study shows the results after a finite element analysis on three patients with successful follow-up after receiving custom-made cones for surgery. The performed solution for the surgery was compared to traditional approaches for knee revision.

Patient 1 and patient 3 show similar trends in the results. Quantitatively, the use of custom-made cones (technique A) led to higher stresses in the tibial metaphysis and in the tibial diaphysis than the use of cemented stems (technique B) and press-fit stems (technique C). This trend can be justified by considering the porosity and the geometry of the cones that can transfer the loads to the bones, hence reducing the risk of stress-shielding and increasing the implant stability. The same considerations can be done for the femur bone for

Table 3 Maximum von Mises stress (in MPa) in the stem for the different techniques among the three patients for femur and for the tibia (in this case only patient 1 and patient 3 are considered)

	Technique A			Technique B			Technique C		
	Full-extension	Gait	Chair-rising	Full-extension	Gait	Chair-rising	Full-extension	Gait	Chair-rising
Patient 1-femur	13.98	9.04	28.02	20.45	46.98	98.43	35.73	50.78	117.07
Patient 2-femur	13.58	13.82	46.30	17.88	22.83	107.95	51.86	46.74	132.50
Patient 3-femur	5.46	4.56	2.32	19.37	31.51	60.69	30.89	45.31	62.82
Patient 1-tibia	0.18	0.17	0.09	24.09	52.12	26.27	40.85	53.05	22.81
Patient 3-tibia	12.32	8.02	4.26	19.56	33.07	14.46	17.95	28.35	12.20

Table 4 Average von Mises stress (in MPa) in the stem for the different techniques among the three patients for femur and for the tibia (in this case only patient 1 and patient 3 are considered)

	Technique A			Technique B			Technique C		
	Full-extension	Gait	Chair-rising	Full-extension	Gait	Chair-rising	Full-extension	Gait	Chair-rising
Patient 1-femur	2.35	2.01	5.03	7.61	12.15	28.06	7.70	11.35	35.95
Patient 2-femur	8.20	6.63	6.43	9.68	8.86	24.74	7.99	6.42	24.68
Patient 3-femur	0.61	0.80	0.49	7.76	10.45	22.01	5.82	7.78	18.01
Patient 1-tibia	0.01	0.02	0.01	11.07	16.64	8.31	11.36	17.53	6.86
Patient 3-tibia	1.19	1.32	0.63	9.89	11.55	5.22	7.71	9.57	4.21

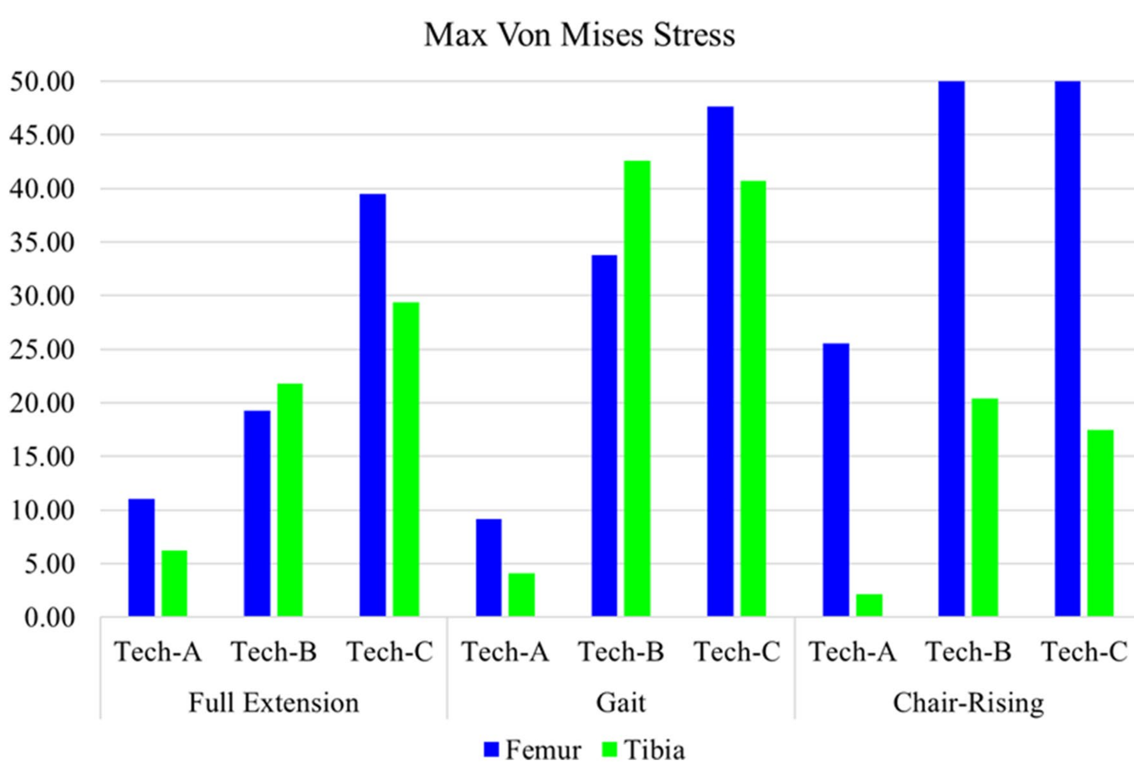

Fig. 8 Comparison of the Maximum von Mises Stress calculated as mean value among the maximum reached by the three patients for femur and for the tibia stem. To easy compare the values the scale is limited to 50 MPa; the femoral values for the chair-rise movement, in case of technique B and C exceed such value. Please check Table 3 for individual values

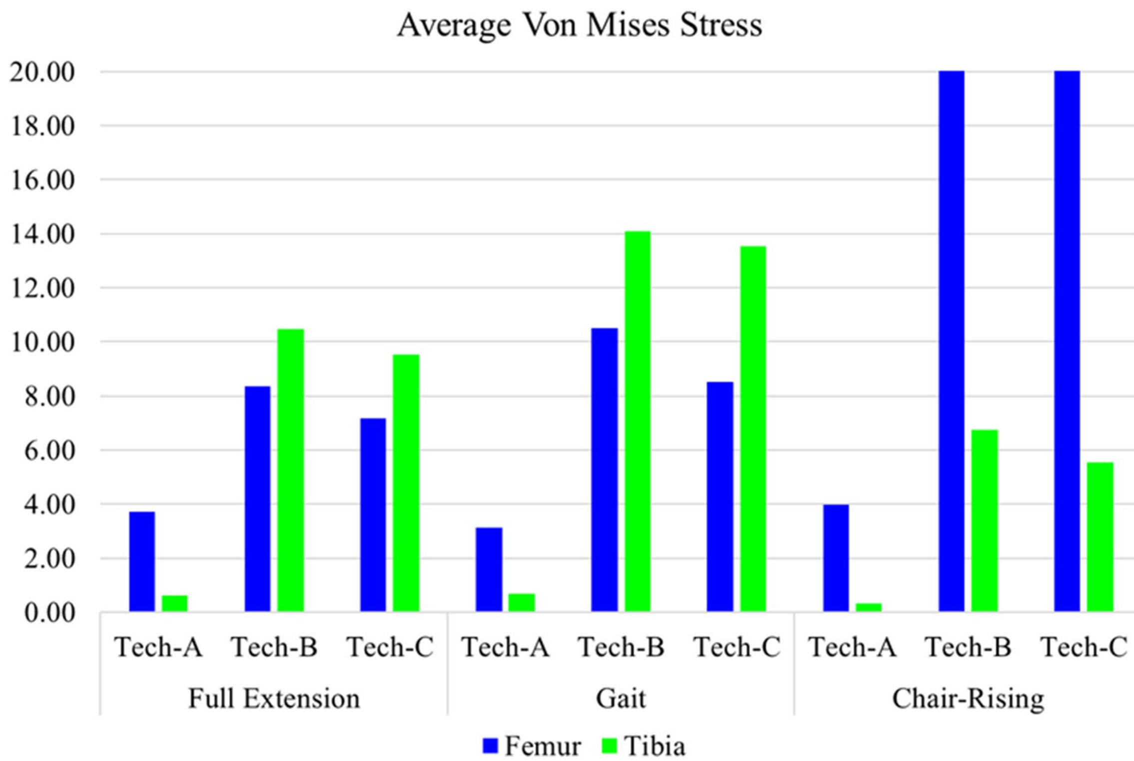

Fig. 9 Comparison of the average von Mises Stress calculated as mean value among the average calculated by the three patients for femur and for the tibia stem. To easy compare the values the scale is limited to 20 MPa; the femoral values for the chair-rise movement, in case of Technique B and C exceed such value. Please check Table 4 for individual values

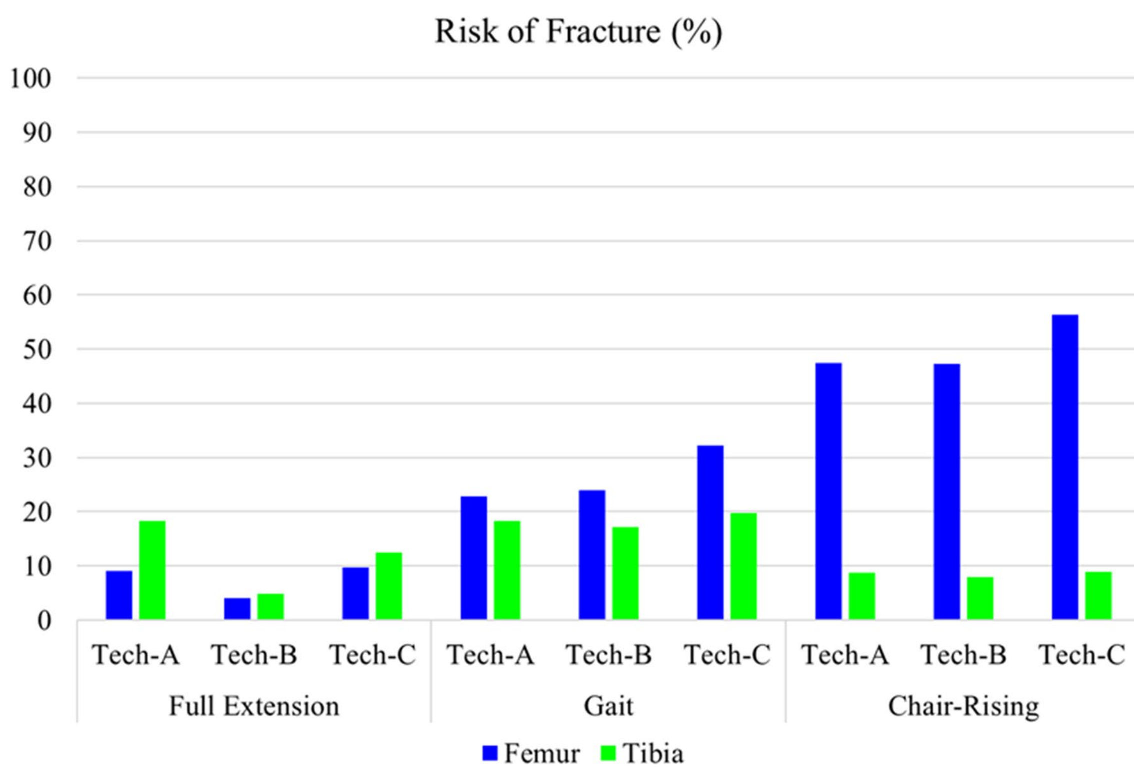

Fig. 10 Comparison of the risk of fracture, expressed in %, calculated for each combination of techniques and daily tasks among patients

which the values of the average stress are higher when the custom-made cones are employed than with the other two revision techniques.

Qualitatively, homogeneously distributed stresses on the femoral and tibial bones are present when custom-made cones are used. The physiologic distribution could prevent the patient from feeling pain and from the risk of loosening. Moreover, especially on the femur, technique A is the only one that results in low stress gradient on the bone during the flexion movement, improving implant stability and inducing a lower risk of bone fractures.

When analyzing in detail patient 2, quantitatively, the stresses on the metaphysis are always lower in the custom-made cone application than the other techniques and the stresses on the diaphysis are higher only in the full-extension configuration. The different behavior with respect to the other two patients could be associated to the severe bone loss and the fracture of patient 2's femur occurred during the first stage (prosthesis explantation). This condition required an oversized femoral cone that engaged the diaphyseal canal in a more proximal part preventing to obtain a complete scratch-fit in the fracture region.

Generally, the results could be estimated as in agreement with other literature studies. In fact, similar trends for stress induced by cemented or press-fit stem can be found in the literature [28, 29] and consensus on improved behavior on bone-metal interface when porous metal is also reported in the literature [13]. The use of custom-made cones induces lower stress along the stem compared to the other two techniques. The higher stress especially induced by the press-fit technique could alter the bone remodeling as it induces stress shielding [41, 42, 44].

Limitations of the study are nonetheless worthy to be highlighted, mainly related to the fact that only three patients on the eleven of the retrospective clinical study were analyzed; but three load configurations and three different surgical approaches used for severe revisions were analyzed. All material models are considered linear elastic, but this method is commonly accepted in different literature studies. Soft-tissues and patella were not actually implemented in the model, but their contribution was nonetheless implemented in the boundary conditions. Even if there are some restrictions adopted in the numerical model, the settings are based on previously validated numerical models [13, 32–34, 36] and, therefore, the obtained results should be considered reliable compared to literature trends and clinical outputs.

Conclusions

This study aimed at the understanding of the benefits gained by the use of the custom-made cones against the performance of more traditional techniques, such as the use of cemented or cementless stems. After a clinical retrospective study on eleven patients, by implementing custom-made cones in severe knee revisions, no instances of loosening, component migration, or mismatches between preoperative planning and intraoperative findings were clinically registered.

The developed numerical biomechanical study supports the clinical trend. In fact, the obtained homogeneous stresses distributions and lower stress gradient over the bones could reduce the probability of bone fractures around the implant and the probability of implant loosening once customized porous cone are used. Furthermore, the absence of stress peaks could be related with potential perceived lower pain.

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Compliance with ethical standard

Conflict of interest Giorgio Burastero has received research grants and has royalties from Adler Ortho (Milano, Italy). Silvia Pianigiani is a paid employee of Adler Ortho (Milano, Italy). Bernardo Innocenti has received research grants and speaker honorarium from Adler Ortho (Milano, Italy). Cristiana Zanvettor, Luca Cavagnaro and Francesco Chiarlone declare that they have no conflict of interest.

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Affiliations

Giorgio Burastero[1] · Silvia Pianigiani[2] · Cristiana Zanvettor[3] · Luca Cavagnaro[1] · Francesco Chiarlone[1] · Bernardo Innocenti[3]

[1] Orthopedic and Traumatology Unit 2, Prosthetic Surgery, Santa Corona Hospital, Pietra Ligure, Italy

[2] Adler Ortho, Cormano, MI, Italy

[3] BEAMS Department (Bio Electro and Mechanical Systems), École Polytechnique de Bruxelles, Université Libre de Bruxelles, Av. F. Roosevelt, 50 CP165/56, 1050 Brussels, Belgium