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Technical Note

Reporting checklist for verification and validation of finite element analysis in orthopedic and trauma biomechanics

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ABSTRACT

Finite element analysis (FEA) has become a fundamental tool for biomechanical investigations in the last decades. Despite several existing initiatives and guidelines for reporting on research methods and results, there are still numerous issues that arise when using computational models in biomechanical investigations. According to our knowledge, these problems and controversies lie mainly in the verification and validation (V&V) process as well as in the set-up and evaluation of FEA. This work aims to introduce a checklist including a report form defining recommendations for FEA in the field of Orthopedic and Trauma (O&T) biomechanics. Therefore, a checklist was elaborated which summarizes and explains the crucial methodologies for the V&V process. In addition, a report form has been developed which contains the most important steps for reporting future FEA. An example of the report form is shown, and a template is provided, which can be used as a uniform basis for future documentation. The future application of the presented report form will show whether serious errors in biomechanical investigations using FEA can be minimized by this checklist. Finally, the credibility of the FEA in the clinical area and the scientific exchange in the community regarding reproducibility and exchangeability can be improved.

1. Introduction

The importance of finite element analyses (FEA) for biomechanical investigations has increased considerably worldwide in recent years. From 1980 to 2009, the number of worldwide studies using FEA seems to have increased geometrically [1]. The advantages of numerical simulations compared to experimental and clinical studies are first, that systems are reduced to mechanical models and thus problems can be considered isolated from other influencing factors. Second, parameter studies are possible that can only be implemented in a very costly experimental or clinical set-up. In particular, the FEA can reduce personnel and material requirements for experiments with human material or samples of animal origin. Third, numerical simulations allow considerations that cannot be justified in animal experiments or clinical trials due to ethical guidelines. Henninger et al. [2] already opined that computational models will become fundamental tools in biomechanics to address future research questions and clinical applications.

There are already several initiatives and guidelines for reporting on research methods and findings [1,3,4], that provides a compilation of reporting parameters for broad distribution and use to completely and accurately assess computational models based on general guidelines. Erdemir et al. [1] presented a highly detailed list of parameters to be included in this process. They described the background of each parameter in detail, thus providing a basis for worldwide reporting guidelines. Furthermore, methods for statistical validation [5] and validation metrics between simulation and

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experiment [6] were developed. The problems of the lack of accuracy also repeatedly lead to the fact that computational models are not recognized in the clinical area [7]. Therefore, the inclusion of verification and validation is a requirement for the credibility of a proposed model especially when results are to be transferred to the patient [2,8–10]. The standardization of numerical analysis in biomechanics is a current issue in the global community, and improved guidelines and standards for good reporting practices in this area need to be developed [11].

In addition to the advantages of numerical simulations mentioned above, there are still numerous issues that occur when using computational models in biomechanical investigations. Due to many commercially available numerical simulation software packages for solving structural-mechanical and dynamic problems, there are equally large differences in pre-, solution, and post-processing algorithms. However, these differences are not the main problem, but rather the fact that there is currently no checklist and report form available enabling a uniform procedure for studies using numerical simulation. This resulted in inaccuracies in modeling and simulation, which could be shown in a comparison of a FEA of the human femur performed by seven participating laboratories with validation [12,13]. These studies showed "that the expectations on the precision of finite element models of the human femur are not yet fully developed as desired by the biomechanics community" [13]. A further example is a case study shown by Zdero and Bougherara [14], wherein a practical approach is demonstrated to combine mechanical testing and FEA of an intramedullary nail for fixing femoral shaft fractures.

Based on these problems, members of the Cluster 'Numerical Simulation' in the Network for Musculoskeletal Biomechanics (MSB-NET) were developing a checklist trying to increase the accuracy and transparency of finite element models. To the authors' knowledge, there is no detailed defined verification and validation procedure in the form of a checklist for FEA, especially for investigations in Orthopedic and Trauma (O&T) biomechanics. Also, problems and controversies are mainly caused by the verification and validation (V&V) process and in the evaluation of the FEA. Based on this motivation, this paper will present and define recommendations and their explanations on these topics. Another primary driver for the development of this checklist was existing guidance on V&V or reporting (e.g., ASME VV 10-2006 [3], FDA Guidance [4], Erdemir et al. [1]) which are not appropriate to serve as a tool during the different stages from planning to reporting of FEA. This checklist is therefore proposed to serve as a convenient tool for set-up and documentation of required steps during FEA in the field of O&T biomechanics. The development was based on experiences in the use of simulation software and corresponding guidelines in O&T biomechanics. Hence, the structure of the checklist was also developed following the main steps of commercial FEA software packages, e.g., ANSYS (ANSYS, Inc., Canonsburg, PA, USA) or ABAQUS (Dassault Systèmes (DS), Vélizy-Villacoublay, FRA). The recommendations presented in this checklist were jointly developed and agreed upon by the MSB-NET.

In summary, this work aims to evolve the valuable considerations of Erdemir et al. [1] to generate a convenient checklist summarizing existing and extended considerations. Therefore, this checklist can be used for future FEA studies to increase exchangeability. Note that the checklist presented below does not include all necessary reporting parameters. For further details, existing guidelines and publications on credible practice and reporting parameters [1,3,15] for modeling and simulation in O&T biomechanics can be consulted. Although some of these guidelines are common sense, we have found that many are often overlooked or misconstrued, even by experienced practitioners. We expect this checklist, which can be systematically used by all MSB-NET members and the community worldwide, to significantly increase the accuracy of biomechanical models in future studies. A uniform report form can also improve scientific exchange in the community regarding reproducibility and data provenance and speed up the overall troubleshooting process.

2. Structure of report form

Based on the current challenges a report form was developed by MSB-NET members for FEA in O&T biomechanics, which is subdivided into four main parts: study objective, simulation model, model verification and model validation, simulation results and reporting. To avoid confusion about the terms used, short definitions partly based on ASME VV-10-2006 [3] and Hicks et al. [10] are listed below:

- *Study objective:* Posed research question to be answered by the model and simulation.
- *Simulation model:* The conceptual, mathematical, and numerical representations of the physical phenomena needed to represent specific real-world conditions and scenarios. Thus, the model includes the geometrical representation, governing equations, boundary and initial conditions, coordinate systems, loadings, constitutive models and related material parameters, spatial and temporal approximations, and numerical solution algorithms.
- *Model verification:* The process of assessing whether a computational model accurately represents the underlying mathematical model and its solution.
- *Model calibration:* The process of choosing model and simulation parameters that provide the best match to experimental or other reference data.
- *Model validation:* The process of determining the degree to which a model is an accurate representation of the real world from the perspective of the intended uses of the model.
- *Simulation results:* The output generated by the computational model.
- *Reporting:* Systematic report on the biomechanical model creation, used verification and validation process, and determined simulation results.

The FEA report shall be executed in such a way that the numerical model can be fully understood. If possible, the structure according to the reporting scheme displayed in Fig. 1 should be followed.

3. Checklist and methodology for verification and validation

Briefly, verification is about solving the equations right; validation is about solving the right equations [16]. Based on these definitions, the following checklist describes mandatory steps to verify and validate a numerical analysis in O&T biomechanics after the model has been developed and the results have been obtained. Thus, it is not the aim of this checklist to specify how a biomechanical model should be built, as this should remain the task of computational engineers. However, all steps performed in a numerical simulation should also be reported in journals with a clinical focus in a comprehensible way and with detailed information about the model. If necessary, additional descriptions should be provided to the scientific community within the appendix. The proposed checklist and the methodological approach therein are derived from the presented MSB-NET report scheme for FEA (see Fig. 1). Ideally, all steps should be performed in the V&V process. In some studies, not all steps may be necessary or useful or even possible to carry out. In such cases, a justification must be added as to why a certain step has not been included.

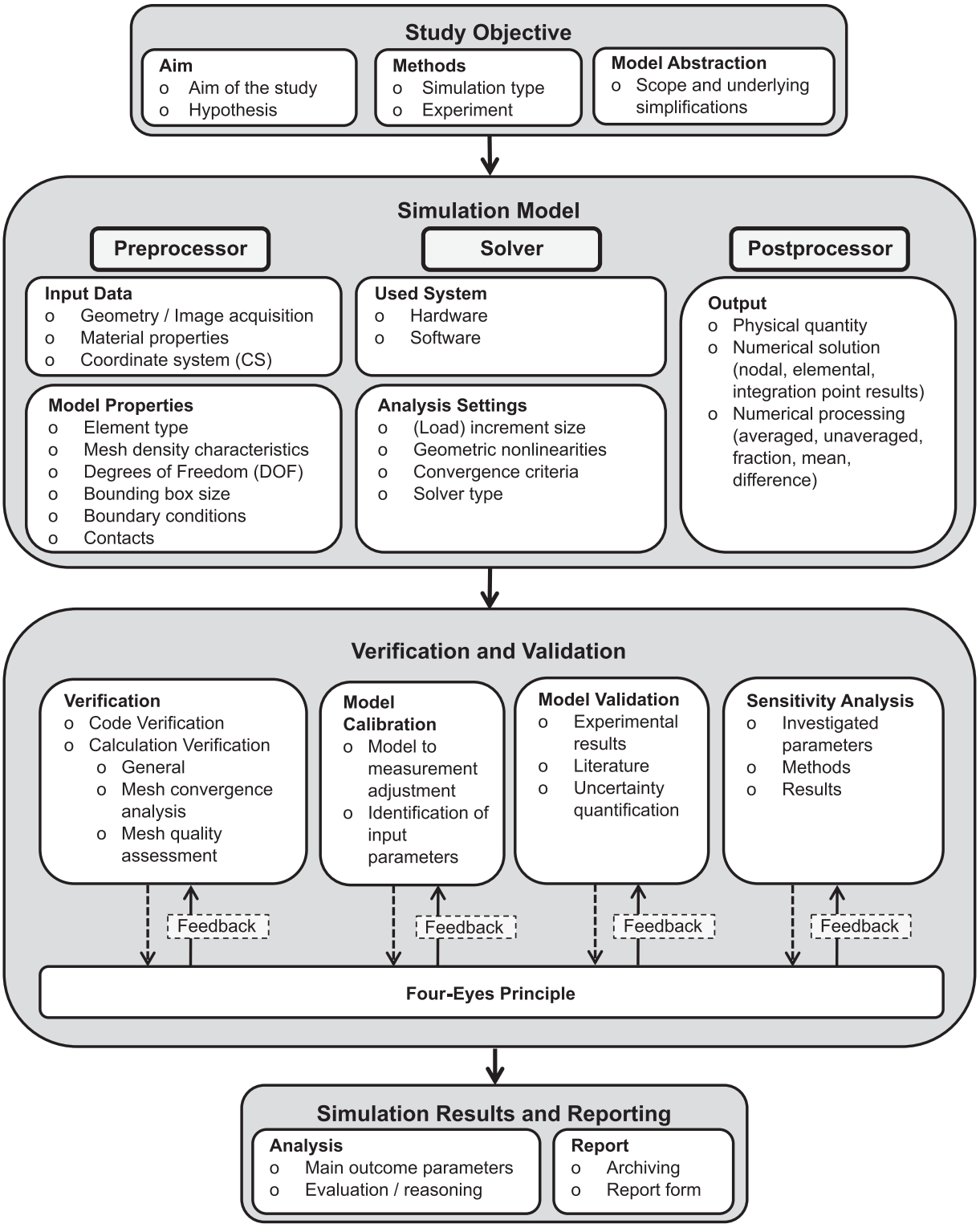

Fig. 1. MSB-NET checklist for reporting of finite element analyses.

3.1. Verification

Following ASME VV-10-2006 [3] the verification process is divided into two parts: code verification and calculation verification. Further on, the verification of the code and the calculation are mandatory steps for FEA in O&T biomechanics.

3.1.1. Code verification

User-defined add-ins, subroutines or external post-processing software added to the model have to be previously verified by tests where the outcome is known a priori. Users can expect verified code from commercial finite element solvers and established open source FEA solvers and therefore exclude them from the verifica-

tion process for this checklist. For code verification, the determination of the discretization error as part of a mesh convergence study is known as an appropriate approach [17]. Nevertheless, the user should keep in mind that undetected errors in the code may change the runtime behavior of the software and can affect the result.

3.1.2. Calculation verification

The application of calculation verification on a finite element model in O&T biomechanics has the goal to estimate the numerical error associated with the discretization. A subdivision in three parts is useful and applicable: general calculation verification, mesh convergence analysis and mesh quality assessment.

General calculation verification: Force and displacement residuum must be checked as well as whether force application equals force reaction (action = reaction). Any examination of the results derived from numerical simulations should include a plausibility check. This includes, for example, estimating the scale of the deformation by rough analytical calculations based on geometrically simplified bone structures (tubes, cylinders, plates). Checking the defined unit system is also a possibility to avoid common mistakes. For nonlinear calculations, it is advantageous to control the increment size manually to obtain an efficient and stable solution process. It is recommended to choose at least ten increments (sub steps) per load step and two further refinements of the increment size for implicit FEA using iterative solvers. In this way it is possible to find the most efficient solution process or relationship between increment size and convergence.

Mesh convergence analysis: Mesh convergence analysis is a prerequisite for using FEA as a numerical tool. The objective is to ensure sufficient discretization and to minimize the influence of the mesh density on the results. This is because with increasing mesh density both global and local outcome parameters converge to certain levels. In this regard, system stiffness (load vs. displacement in the direction of load application), mean overall deformation, mean strain energy, and maximum structural error are usually considered as global outcome parameters. Local outcome parameters are generally the study's results such as force, displacement, or strain and stress values at defined points or regions of interest (POIs/ROIs). The convergence of global outcome parameters is a requirement that does not necessarily imply convergence of the local outcome parameters. For the latter, further global mesh refinement, as well as local mesh refinement, can be considered.

The following three steps are necessary to assess mesh quality in terms of convergence for a finite element model consisting of one component:

Step 1: Define an initial mesh size as a function of the component geometry. The initial mesh size should be chosen to adequately represent the geometry of the component with a minimum number of mesh elements by using solid elements. Adaptive meshing is also preferable to limit the number of elements. The element order (e.g., linear or quadratic) should be chosen based on the topic and the model size. For instance, elements of quadratic order may be necessary for complex geometries and bending deformations.

Step 2: Refine the mesh at least three times by increasing the number of nodes with a ratio of at least 1:1.3–1:1.5.

Step 3: For all result parameters a convergent behavior should be observed for at least three consecutive refinement steps. Common values for a convergence criterion are in the range of 1–5%. Mesh refinements (Step 2) are repeated until this criterion is met for all outcome parameters. At the point of the component geometry with the lowest thickness there should be at least two elements for a convergent solution. More elements may be necessary for studies with interests in bending deformations to exclude phenomena like locking. The mesh generated after the last refinement step is then considered as a converged mesh applicable for subsequent FEA. If a non-convergent behavior is present, more data points and thus a higher mesh density is required. Existing singularities, i.e., points or regions in the model where the values tend to be infinite, must be excluded from the evaluation of the results. It must be ensured that no singularities are present in the POIs/ROIs for the examination.

If the overall deformation but not a local outcome parameter (e.g., strain or stress in a local hot spot) converges within Step 3, stepwise local mesh refinement (see ratios above) can be considered. In this way, further global mesh refinement can be avoided, which has little effect on local convergence but significantly increases the computational effort. While other outcome parameters should be unaffected, the convergence of the local outcome parameter can be evaluated. Note that for local stress evaluation typically the decreasing difference between averaged and non-averaged values indicates good convergence characteristics. For stress evaluations, the ratio between averaged and non-averaged stress values should be below 5%.

When several components with widely varying geometric dimensions are present (e.g., osteosynthesis with bone, plate, and screw geometries), it is generally difficult to identify one consistent initial mesh to perform a meaningful mesh convergence analysis. Either the initial element size is too small for the largest component that convergence may already have been achieved, including too many nodes, or the initial mesh is too coarse to accurately reproduce the geometry of the smallest component. Instead, it is recommended to define an individual initial element size for each component separately (Step 1). Mesh refinements (Step 2) are then performed simultaneously for all components in a ratio of at least 1:1.3–1:1.5 based on the individual element sizes until the abort criteria (Step 3) are met for all outcome parameters. This procedure may generate relatively large numbers of nodes on those components that are not crucial for the POI/ROI results. Hence, the mesh of these components can be re-coarsened one by one using their previous refinement steps in reverse [18]. A relative error of less than 0.5–1% for each POI/ROI result should be maintained for the last coarsening step of each component tested to ensure unchanged model accuracy.

Further considerations have to be taken into account when formulating contact between different mesh regions (self-contact or towards different components). This may include the conformity of the mesh(es), being in contact to realize a uniform contact pressure distribution on the corresponding nodes. If different mesh densities are present, the finer discretized mesh and the less stiff component is typically selected as slave for master-slave assignments [19].

Mesh quality assessment: As shown in Burkhart et al. [20] there is still a lack in the implementation of mesh quality assessments in the field of O&T biomechanics. After a mesh convergence analysis with complex meshes, which includes manual adjustments, the mesh quality (e.g., shape, aspect ratio, element Jacobians) must be checked and documented. High mesh quality is particularly important for individually chosen POIs/ROIs.

3.2. Model calibration

According to Hicks et al. [10] model calibration is a crucial step in which the results of simulation models are adapted to real measurement data. Measured data, e.g., a load-deformation curve, is taken as reference and the parameters of the simulation model are modified until the best possible agreement between reference and simulation is achieved. Models and simulations must be carefully calibrated before validation is performed. The data used to calibrate a model must not be used to validate a model or simulation.

3.2.1. Model validation

The validation aims to confirm the calculated results experimentally and to check the predictability of the model. It is specified that the model has to be validated to compare the computational model with the observation, in this case, a biomechanical experiment. In the first step for the numerical simulation, a suitable experimental set-up has to be created, which allows to validate the computational results. For this purpose, e.g., displacement measurements (optical, tactile, inductive), modal analyses (acoustic) or strain measurements (optical or by strain gauges) are applicable to validate FEA. These data should be derived using experimental set-ups. When human tissue is examined in the simulation (age-dependent material properties, anatomical dimensions, etc.) the experimental data for the validation process should preferably be collected in-house under similar conditions regarding the experimental set-up and biostatistical questions. Additionally, results from literature derived by investigating similar cases *in silico* and experimentally can be compared with the results obtained with the own model. This procedure is only possible if the most important model parameters (for example boundary conditions) are known within the simulation, otherwise this comparison is not valid for a validation process. For example, a finite element model of the knee joint requires all degrees of freedom (DOF) of each solid body and directions of force with their values and the point of action. Moreover, all possible constraints and the biostatistical parameters within the study should be known to keep the deviation in results due to changing simulation parameters small. It is advisable, that experimental outcomes for tests should, if possible, only be provided to modelers after the numerical simulations have been performed with a verified model [3], in order to perform model set-up and verification in a blinded manner.

If there is no opportunity to validate the model in an experimental study, again published data of a comparable study from the literature can be used. The report should include justifications as to why the literature data is suitable for validation or whether there are significant differences in set-up or evaluation. In general, conducting experiments for validation in O&T biomechanics is very complex. In addition to the often complex experimental set-up, there are also sources of error such as the rapid decomposition of the biological material or non-uniform geometries with varying material properties.

3.2.2. Statistical metrics and model evaluation

Depending on the research question several statistical metrics exist that can be used to quantify the agreement between the simulation results and experimental outcome [21,22]. For example, the differences between simulation results and corresponding experimental measurement can be quantified using the squared Pearson correlation coefficient (Pearson's r), coefficient of determination (R^2) as a measure of magnitude and shape differences, and Sprague and Geers metrics of magnitude (M), phase (P), and combined error (C) [23,24]. Spraque and Geers metrics quantify the errors in frequency and phase response between simulation results and measurement. Furthermore, data corridors can be used to generate boundaries based on the mean and standard deviation of a dataset [20]. Simple methods available for error assessment are relative deviations expressed in percent and root-mean-square error (RMSE) as a measure of the difference between values predicted by the numerical model and the values observed by the experimental set-up. The Pearson's r can be used as a tool to determine the relationship between simulation and experimental data as a measure of shape differences. Additionally, the Bland-Altman plot can be used to quantify the difference between the two methods [25].

To compare the experimentally measured and numerically predicted values, a linear regression is recommended, whereby the regression parameters and coefficients must be documented. A discussion should follow based for example on RMSE as an indication of the average residual, and the peak error, as an indication of the maximum residual [7]. The specification of a tolerable maximum error value often depends on the specific study. Therefore, this checklist does not define a generally tolerable maximum error value, but the deviation must be quantified and sufficiently discussed.

This protocol is not intended to provide a comprehensive metric within this checklist for every possible research question. Instead, it is emphasized on reporting all specific details concerning the statistical methods used. Thus, the scientific community can be given the chance to assess the simulation results within the study aims. The verification and validation methods should address the intended use (simulation results) of the model [20]. Additionally, some examples of the described metrics in the field of musculoskeletal biomechanics can be found in different studies [8–10,13,20,26–30].

3.2.3. Uncertainty quantification

Uncertainty quantification involves the empirical determination of the uncertainty in the model inputs, which typically results from natural variability or measurement error, and the subsequent calculation of the resulting uncertainty in the model outputs. If possible, the uncertainties should be presented as mean values with standard deviations or distributions. But even if statistics are not available, an estimate of experimental uncertainty based on previous experiences or an expert opinion is required before comparisons with simulation outcomes can be made [3,17].

3.3. Sensitivity analysis

Sensitivity analysis aims to estimate the influence of uncertain input parameters on the results. A common approach is a parameter study, in which one parameter is varied at a time and the effects on the results are determined. The input parameters subject to the highest uncertainties are to be varied within an appropriate range and the results are to be plotted against the variations and discussed if necessary. These parameters to be evaluated for a sensitivity analysis are defined by the user. The parameter study is suitable if the ranges of input parameters and sensitivities are already known in advance. Literature data and the experience of the simulation engineer are valid sources for this information.

Especially in O&T biomechanics, the material parameters of the bone are uncertain input parameters. The question often arises which material law or material mapping strategy must be applied for modeling bones in FEA. In this case, a sensitivity analysis can answer the influence of uncertain input parameters on the results, as shown by Taddei et al. [27].

Another approach for sensitivity analyses is sampling methods such as Monte Carlo analyses. In these analyses, random samples of input parameters are generated with specific probability distributions, and the corresponding output deviations are determined by using repeated runs of the model. This approach typically requires many (more than a thousand) runs and can become time-consuming due to the high computational effort of simulations [31]. The Latin Hypercube Sampling (LHS) technique is also recommended for sensitivity analyses. This statistical method generates a near-random sample of parameter values from a multidimensional distribution [32].

3.4. Four-eyes principle

The four-eyes principle aims to verify the correct procedure and to avoid possible errors. The entire simulation model must be critically reviewed together with an expert colleague, which includes

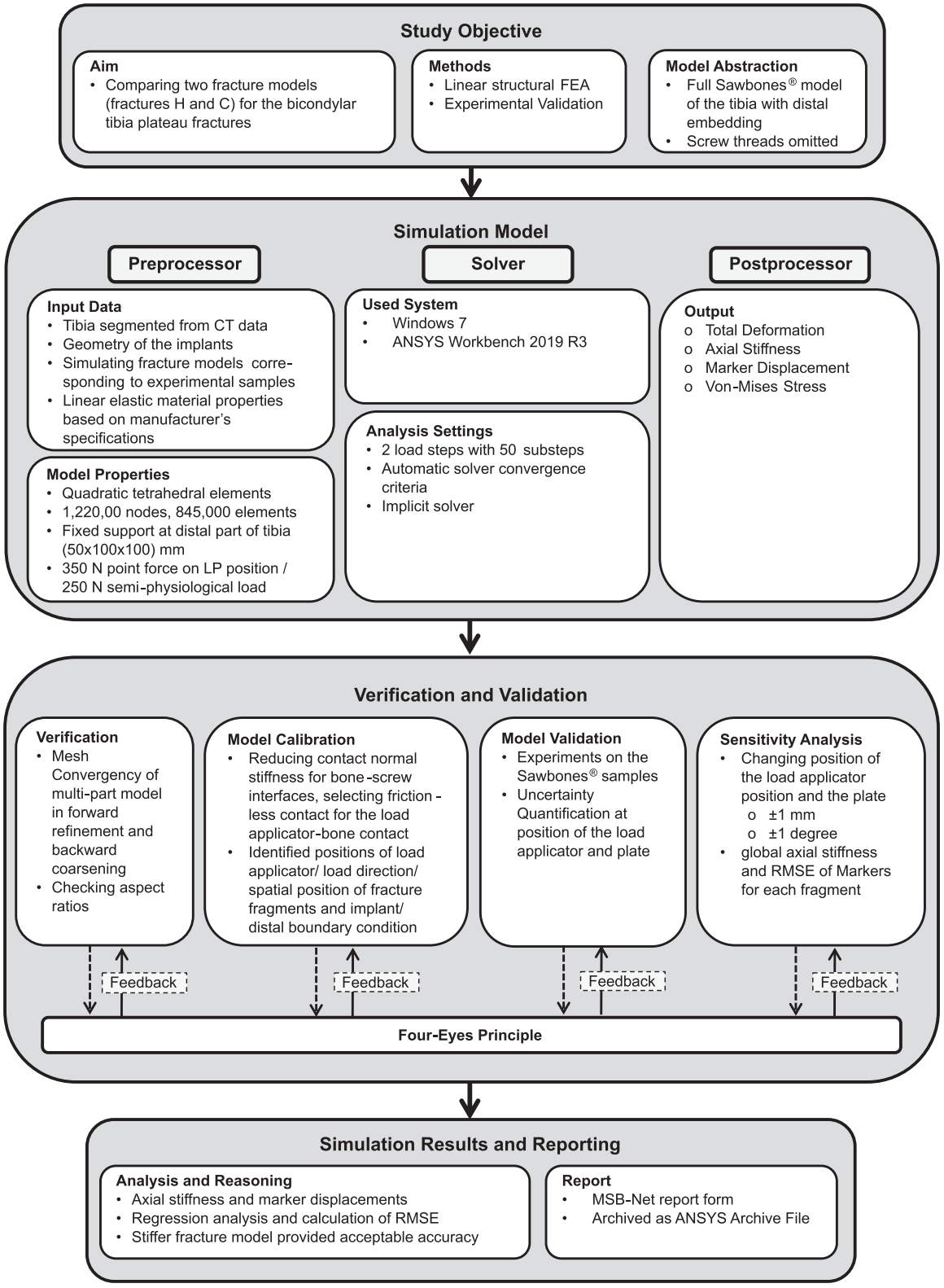

Fig. 2. Example of MSB-NET checklist for reporting of finite element analysis based on the study by Samsami et al. [33].

primarily each step of the V&V process. After each step, the colleague confirms that all methods, inputs as well as evaluations, and finally the points listed in this checklist have been conscientiously processed. If no other expert colleague is available in the own working group, an expert from another laboratory should be considered. If four-eyes-principle was not applied due to a lack of expert colleagues, a comment and justification must be added to the report form.

4. Simulation results and reporting

The section simulation results in the reporting scheme should contain the main outcome parameters and the reasons why the evaluations conducted were chosen in the present study. The type of each of the selected strains, stresses, and contact pressures must be justified. The type of evaluation used regarding averaging methods and locations (integration point, node, element/nodal results, averaging along a path, etc.) is also part of the documentation. If contacts are implemented in the FEA, e.g., evaluation of the penetrations and contact behavior (sticking/sliding), a justification why these models are acceptable must be added.

The report shall be written in such a way that the numerical model can be fully understood, and that all relevant information can be assessed by other colleagues or research groups. As an example, the checklist is filled out with a FEA study (see Fig. 2) from Samsami et al. [33]. Also, Woiczinski et al. [26,33] can be used as an application example to fill out your individual checklist. In addition, a template of the report form is provided (see supplementary materials), which serves for future documentation and can be filled out and used by anyone.

5. Summary and conclusion

The presented checklist and report form for FEA in O&T biomechanics provides a uniform basis for future documentation. It is intended to promote scientific exchange, good scientific practice, and reduce major errors in the modeling process. Since this checklist was created to further develop the valuable considerations of Erdemir et al. [1], an evaluation was performed by filling out the developed report form with the example study used there. On the one hand, the identified advantages of the presented report form are that it:

- is a convenient tool to get started with FEA in O&T biomechanics;
- provides additional recommended steps to perform in FEA, e.g., mesh quality assessment, model calibration and four-eyes-principle;
- includes all the recommended steps of FEA in O&T biomechanics so the user can specify all the steps to be performed more quickly in advance;
- is capable to document the key results and can be used as a report independent of a publication or final project report.

On the other hand, it will be a constant challenge for the user to fill in the given report form with a sophisticated biomechanical study. Depending on the objective, the user himself must find a good structure and decide which report form is advantageous.

Due to the continuous development of numerical simulation, especially in the field of biomechanics and the aim of clinical application, it is necessary to keep the checklist up to date. For this purpose, an international collaboration of research groups conducting FEA in the field of O&T biomechanics may be useful for the further development of this checklist. In the future, a general guideline for FEA in O&T biomechanics could be developed based on this checklist and report form.

Declaration of Competing Interest

None declared.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.medengphy.2021.03.011.

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