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Report on the Use of Numerical Analysis for Strength Evaluation of Orthopedic Implants

Yoichiro Matsumoto, Chairperson
Takashi Yamane, Vice-chairperson
Subcommittee on Application of Numerical Analysis to Non-clinical Evaluation

1. Introduction

For the strength evaluation of orthopedic implants such as hip prostheses, mechanical tests provided in standards such as the Japanese Industrial Standards (JIS), International Organization for Standardization (ISO), and American Society for Testing and Materials (ASTM) are often performed. However, numerical analysis has been increasingly used to identify the worst case before mechanical tests for manufacturing implants with new shapes. In addition, numerical analysis is expected to be used in the future for the prediction of changes *in vivo*, such as looseness after implantation, and for treatment.

Regarding the use of numerical analysis in the strength evaluation of implant products, our subcommittee has examined its usable range on which a consensus can be built. We focused on the discussion about evaluation in relation to manufacturing and decided to save the discussion on the evaluation of the changes of implants *in vivo* and changes in a living body for another time. On that basis, we began to mathematically specify the scope of deformation and materials that can be analyzed by numerical analysis and then put our idea on safety factor and life estimation in order for use variations. For actual evaluation, we discussed ideas on the use of numerical analysis for materials that have been used before and those that have not.

2. Classification of the intended purpose of numerical analysis

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Numerical analysis has been broadly applied in the medical field. In particular, mechanical analysis has been broadly used from basic studies to clinical applications, for example, macroscopic motion analysis; behavioral analysis of organs in a living body such as bones and simulation of blood flow in circulatory system; and microscopic intracellular mechanical responses.

In particular, numerical analysis is greatly expected for the prediction of the behavior of implants installed in a living body. Prosthesis and spinal instrumentation surgeries are major treatment methods in the orthopedic field. The number of these surgeries has been annually increasing. The number of cases of prosthesis surgery is now estimated to be 150,000 or more per year in Japan. These surgeries have a great affinity for numerical analysis, from designing the prosthesis to predicting behavior *in vivo*.

Owing to the development of metallic materials and the progress of design software, new implants have been developed in a cycle much shorter than ever. These implants aim to 1) facilitate the surgical technique, 2) obtain high functionality with further conformity to the living body, and 3) sustain their functions *in vivo* throughout a patient's life if implanted for a long time. In addition, many applications for approval have been filed for these implants.

On the other hand, there are complications including damage, infections, abrasion, and looseness in these implants. These complications often result in reoperation or implant replacement. Implant replacement is performed in approximately 10% of cases ten years after index surgery. The causes of implant complications comprise three factors: 1) implant-related factors (material and shape), 2) surgery-related factors (surgical technique, perioperative patient management, and environment of operating rooms or hospitals), and 3) patient-related factors (bone and muscle strength, biological reaction, and patients' personalities and behaviors). Big data, in particular, patient registration systems (registries) for all patients, are essential for the analysis of such complications. Data from Scandinavian countries such as Norway and from the United Kingdom, where the system is nationally operated, greatly contribute to analysis and countermeasures. Because the registration database is operated by a general incorporated foundation in Japan, we have a major challenge in improving the registration rate.

Mechanical tests of implants are the mainstream in the evaluation of implants. Standardized durability tests for hip prostheses are provided in the standards including the ISO and JIS. Although these tests reflect events *in vivo* to some degree, there is no

doubt that they are limited to primary factors among complicated events *in vivo*. In addition, these durability tests require time from several months to a year and require a large cost. It is, therefore, a fact that some doubts have been thrown to the condition settings of durability tests for diversifying and increasing implants.

We think that among the causes of malfunctions, only the characteristics of implants and changes *in vivo* should be targeted in numerical analysis. However, the latter requires the analysis of events, including the biological response to patients' personalities and living environments, in which there are quite a few immature academic fields. Thus, this report treats only applications to non-clinical evaluations, i.e., the characteristics of implants. We define this point as a scope of contents treated in this report. (The latter will be discussed in the future.) This report, therefore, has been prepared to target design evaluation at the stage of implant design.

3. Current situation of numerical analysis performance and application to strength analysis of orthopedic implants

3-1 Biomedical materials and mechanical response characteristics

Currently, the following materials are used for orthopedic implants: metals such as titanium and cobalt–chromium alloys; ceramics such as alumina and zirconia; polymers such as ultra-high molecular weight polyethylene (UHMWPE), polyether ether ketone, and polylactic acid; and composite materials such as carbon fiber reinforced resin (continuous fiber reinforced resin or short fiber reinforced resin). To a method to describe mechanical response characteristics (deformation behavior against external forces) of these different kinds of materials in a continuum mechanics manner (method to predict the stress–strain relation), theories of mechanics of elasticity (linearity/non-linearity, isotropy/anisotropy), plasticity, viscoelasticity, damage, etc. can be applied. The mechanical response characteristics of materials can be classified as follows:

(1) Elastic deformation:

This is a simple, elastic deformation without microscopic damage such as dislocation, microcrack, void, and craze. In this case, an object can completely return to its original shape when unloaded. Elastodynamics should be applied to this case. When a stress–strain curve represents (or approximately represents) a straight line, this is referred to as linear elasticity. In this case, there is a

proportional relation between stress and strain, which can be easily handled mathematically. In the analyses of industrial materials using the finite element method (FEM), numerical analysis is usually performed by assuming that an object is a linear elastic body.

(2) Irreversible non-linear deformation:
In this case, microscopic damage occurs, develops, and accumulates. In most cases, this is macroscopically called plastic deformation. With applying of plasticity and damage mechanics, FEM analysis has been attempting to reproduce non-linearity and irreversibility (non-elasticity) occurring in the stress–strain relation. Studies have been attempting to reproduce these relations using elastoplastic analysis, which should be validated.

(3) Macroscopic breaking (structural rupture)
Supporting loads become impossible because of ruptures caused by the connection of microcracks and voids. This is a field where the FEM analysis is difficult to be applied.

Generally, the deformation proceeds from (1), through (2), to (3) in metals or polymers but directly from (1) to (3) in ceramics. In composite materials, the deformation proceeds from (1), through (2), to (3); however, the behavior from (2) to (3) is very complicated due to causes such as the drawing of ruptured fibers and fiber rupture of peeled resins at the fiber/resin interface.

It is known that the mechanical characteristics of polymers depend on the loading rate (i.e., polymers show different mechanical response characteristics against slowly and impulsively acting forces). Analysis based on viscoelasticity mechanics is required when different loading rates are expected to act on polymer implants. In addition, there are viscoelastic behaviors such as creep, a gradually increased strain under a certain action of stress, and stress relaxation, a gradually decreased stress under a certain action of strain. Thus, it is important to ascertain the viscoelastic behavior that will occur under the use environment. For most industrial polymers, it is usually possible to perform elastic analysis assuming a static condition, up to a loading rate (deformation rate) of approximately 1 m/s or lower.

3-2 Constitutive equation and property of biomedical materials

The generalized Hooke's law is used as a constitutive equation for all materials if they show linear elastic behavior (or if analysis is performed within a range of linear elasticity). Two material constants are necessary for modeling, Young's modulus and Poisson's ratio, both of which are determined by a simple tension test.

Some models have been proposed for an elasto-plastic body according to the stress–strain behavior after the start of plastic deformation. For example, bodies such as the following are used: elastic–perfectly plastic solid, which shows a constant stress in the plastic region; elastic–linearly hardened plastic solid, which shows linear hardening characteristics; and elastic–non-linearly hardened plastic solid, which shows curve hardening characteristics. Because the elastic–linearly hardened plastic solid represents a straight line in the stress–strain diagram in the plastic region, two material constants, yield stress and strain hardening coefficient (gradient of the stress–strain diagram), are required to represent plastic deformation. The elastic–linearly hardened plastic solid, which is easily treated (i.e., material constants can be easily determined), is a model often used in the FEM analysis. Although the start of plastic deformation can be determined with the use of yield stress when the stress is uniform in simple tension, it is not easy to determine the yield under a complicated multi-axial stress condition. However, the introduction of von Mises equivalent stress allows us to convert a complicated, three-dimensional stress condition to a simple, uniaxial stress condition and to determine the yield using only yield stress. This determination method is called von Mises yield criterion and is often used in the FEM analysis.

Because the mechanical response of a visco-elastic body shows time dependence, the constitutive equation is also expressed as a function of time. In the modeling of mechanical behavior of the visco-elastic body, visco-elastic behavior is expressed as a combination model of a spring element expressing elastic deformation and a dashpot element expressing characteristics of viscous flow (in which the stress is proportional to the strain rate). The simplest models are the Maxwell model, in which one spring element and one dashpot element are connected in series, and the Voigt model, in which these elements are connected in parallel. These models can describe mechanical response characteristics using only two material constants. These models have a limitation of application. Thus, the generalized Maxwell model with increased elements is used to improve precision. However, this model also has a limitation of application because of the increased number of material constants. Practically, the Kelvin model, using two spring elements and one dashpot element, is often used. In this model,

approximation can be done relatively precisely and material constants can be easily determined.

One of the most broadly used constitutive equations of materials showing rubber elasticity is the Mooney–Rivlin constitutive equation, which expresses non-linearity unique to rubber elasticity by showing the principal stress difference as a function of the principal elongation ratio.

3-3 Application of the FEM analysis to the strength analysis of biomedical materials

The following are considered as applications of the FEM analysis to the strength analysis of orthopedic implant materials. However, these include application fields from a viewpoint of current studies. Note that these do not show fields where, among the performance evaluation of orthopedic implants mentioned below, FEM analysis is applied to the strength evaluation with high reliability.

(1) Examination of mechanical behavior in elastic deformation:
This is an analysis using only elastodynamics and is an application for the prediction of deformation amount (displacement amount) against the expected loading weight and the prediction of stress concentration amount due to the presence of voids and corners. For many materials, this analysis assumes a “linear elastic body,” which can be easily treated mathematically (i.e., material constants can be easily determined). At the current stage, the appropriate setting of analysis conditions allows us to predict strength with high reliability and to apply to the strength evaluation, one of the performance evaluations of orthopedic implants, with high reliability.

(2) Examination of the occurrence status of plastic deformation (permanent deformation):
The following should be assumed when only elastic analysis is performed: plastic deformation occurs at points where a stress equal to or greater than yield stress occurs. In an analysis with a combination use of the theory of elasticity and that of plasticity (hereinafter referred to as “elastoplastic analysis”), deformation after the start of plastic deformation can also be analyzed. However, it is an important issue whether the mechanical characteristics of materials can be modeled with good precision. This can be applied to the optimization of designing at the design stage; however, there is a limitation to apply this to performance evaluation.

(3) Examination of the presence of structural ruptures:

The simplest method is one in which only elastic analysis is performed. In this case, the following should be assumed: structural ruptures occur when the maximum stress on the surface of or inside the structural body (maximum principal stress, etc.) reaches the breaking strength. This method allows us to estimate the breaking strength by defining a sufficient safety factor. In the elastoplastic analysis, this method allows us to analyze the loss of the load-supporting function due to a large-scale plastic deformation. As numerical analysis methods using FEM develop, breaking phenomena can be reproduced assuming the loss of each element's mechanical function (for example, an element reaching breaking condition disappears or the modulus of elasticity is set as zero). Studies are now being conducted for the validation of such techniques.

3-4 Implant structure and applicable fields of FEM

The analyses of orthopedic implants comprising more than one component sometimes require various complicated treatments regarding numerical analysis such as the modeling of contacts between components and the consideration of the dynamic change of constraints. For example, an ordinary hip prosthesis comprises combined components made of different materials such as titanium alloy, alumina, and UHMWPE. Currently, it is difficult to apply numerical analysis in consideration of contact between the alumina epiphysis and UHMWPE liners or of changing loads or other factors simulating mechanical conditions of the hip joint. However, numerical analysis can be applied when an implant is deemed to have an integral structure, just like the epiphysis and stem of the hip prosthesis, even if the materials of the implant to be analyzed are different.

3-5 Basic concepts on strength design

This chapter considers medical devices used *in vivo* such as a joint prosthesis and states the basic concepts of strength design.

3-5-1 Most critical strength, allowable stress, and design stress

Generally, in the mechanical strength design, from the most critical strength (Note 1) showing the strength of materials used, we should estimate the boundary allowable stress not causing damage or breaking when the material is used as a component of the structural body and design the structural body so that the working stress occurring in the practical use of devices will be equal to or less than the allowable stress.

The most critical strength should be selected among the tensile strength, yield stress, fatigue limit, impact strength, creep strength, and so on, depending on the mechanical conditions and the environment of usage. These parameters can be experimentally obtained from standard test piece and standard test methods provided in the JIS. Because a complicated stress field acts on the components in a structural body, the most critical strength obtained under a simple loading condition does not always represent the allowable stress. The type of the most critical strength should be appropriately selected according to the situation of their practical use. However, assuming that there is a correlation between the most critical strength and allowable stress (Note 2) and setting a safety factor in consideration of various factors, the allowable stress is determined by the following formula:

Allowable stress = Most critical strength/Safety factor

On the other hand, it is difficult to accurately know the working stress. This requires us to measure the loading and strain under the situation where devices are actually used and to identify by structural analysis. In cases of *in vivo* medical devices, because it is extremely difficult to measure in a living body and as these devices have complicated shapes, we have no other choice but to rely on structural analysis by numerical simulation to estimate the working stress. There, we calculate the stress field occurring in components by loading conditions expected in use, obtain the most risky design stress from a view of strength based on various theories on material strength (Note 3), and have the obtained value be equal to or less than the allowable stress. Cases of *in vivo* medical devices, which are difficult to experimentally validate, have uncertainty of loading in use or loading form. Thus, a great error may be included between the working and design stress. Considering this fact, we should estimate the allowable stress to be lower, i.e., we should keep the safety factor greater. The safety factor mentioned above should, therefore, be determined by the following factors: factors for strength evaluation attributable to the unevenness of the most critical strength and to the uncertainty of breaking form and factors for stress evaluation attributable to the uncertainty of loading conditions and to the precision of structural analysis.

Note 1 Stress is generally used; however, strain may be used as a reference.

Note 2 The correlation is often observed between the most critical strengths.

Note 3 These theories include the maximum principal stress theory, maximum shear stress theory, and maximum strain energy theory.

3-5-2 Setting of safety factor in strength design

It is still controversial whether standard tests in real devices show the worst case under a load condition in a living body; however, it shows a kind of standard status of strength. If standard tests in real devices guarantee the safety of use *in vivo*, the stress obtained in standard tests in real devices can be deemed as the allowable stress. For medical devices for which experiments and measurements cannot be performed in a human body, the allowable stress or safety factor from the most critical strength should be determined through such standard tests in real devices *in vitro*.

In standard tests in real devices with provided loading conditions, it is highly possible to reproduce the stress status acting on real devices with good precision by structural analysis using numerical simulation. Therefore, if a combination of *in vitro* standard tests in real devices and structural analysis using numerical simulation is used, the strength is highly likely to be guaranteed only by the analysis of numerical simulation without standard tests in real devices for cases such as the partial change of the shape of devices. Moreover, similar treatment can be performed for cases of material changes if the strength is evaluated by the safety factor from the most critical strength of the material.

Even if safety is confirmed in standard tests in real devices, the allowable stress should be estimated to be less than the calculated value in the simulation if damage may occur in a human body or under a special use environment (for example, on exercise). In this case, the difference between the stress occurring in standard tests in real devices and that in use in a human body should be identified by structural analysis using numerical simulation in which various working loads in a human body are expected. Furthermore, the estimation of allowable stress from standard tests in real devices and the revision of such tests should be discussed. With the use of sham bones or other parts, experimental conditions are desired to be examined under conditions close to clinical settings as much as possible.

3-5-3 Fatigue life estimation by numerical analysis

(1) Correlation between static stress analysis and fatigue life estimation

To know the limitation of fatigue analysis, we often discuss about whether there is an actual correlation between static stress concentration and fatigue limit. First, although the mechanism of fatigue failure includes many factors, a scientific theory mechanically integrating the mechanism of fatigue failure has not yet been established. However, there is a high correlation between the site of high-degree

static stress concentration and the site of fatigue failure. The fact that there is a coincidence between the site of stress concentration and the fracture site in fatigue tests using real devices may be evidence showing the validity of numerical analysis; however, we cannot always say that the analysis is incorrect if there is no coincidence because failure includes probabilistic elements.

Utilizing data from the fatigue test obtained with the use of a test piece of the material, we can estimate fatigue life using numerical analysis. In this case, it is critical to choose test samples. Regarding treatments such as heat and surface treatments, a test piece, which was similarly treated in the manufacturing process for the product device, is necessary. Test conditions also must reflect conditions in use. Thus, to select the fatigue test method, it is important to select the fatigue modes of compression, tension, rotatory bending, and torsion and their combination. Some cases require the incorporation of a characteristic change *in vivo* and the degradation estimation of biomedical materials, as necessary.

(2) Risk management

Regardless of whether in experiments in real devices or in numerical analysis, the first thing to perform is to bring boundary conditions close to clinical conditions. Despite the accumulated clinical database, it still remains difficult to determine loading and boundary conditions in breaking cases in clinical use. We cannot uniformly estimate the change of boundary conditions associated with bone resorption by the living body (remodeling and loosening). The numerical analysis of devices requires treating a singular solution in boundary conditions, i.e., at a fixed position. It may be a better idea to improve the analysis precision and reduce risks by describing the changing trend of the solution when analysis conditions are changed.

(3) Current limitation to apply numerical analysis

Numerical analysis is advantageous, in particular, in fatigue life estimation, in that tests in real devices can be reduced. The utilization of numerical analysis allows us to perform reasonable evaluation based on scientific evidence comprising quantitative parameters such as stress and strain. Efficiency can be improved in difficult matters of tests in real devices (such as fixed conditions, loading conditions, measurement methods, expended times, and cost).

However, modeling is difficult for very complicated structures (microscopic change of shape, anisotropy of material characteristics, and diversity of manufacturing process). In addition, it is difficult to analyze a lot of undetermined conditions such

as loading and boundary conditions *in vivo*. Thus, the application of stochastic FEA, a stochastic method, can be considered.

(4) Fatigue strength evaluation of a hip prosthesis

As discussions that have been internationally held for fatigue strength evaluation, we will introduce the cases of strength evaluation of a hip prosthesis in ISO/TC 150 (Technical Committee on Implants for Surgery) and ASTM/F04 (Committee F04 on Medical and Surgical Materials and Devices).

Currently, the mechanical stability of surgical implants, including a hip prosthesis, is predominantly evaluated by an experimental method. The ISO and ASTM also conduct standardization based on experimental evaluation in real materials or implants. To measure the strength of implants, quantitative evaluation based on internal stress and strain is scientifically essential. However, current specifications only require us to determine the absolute external loading amount based on the body weight and to observe the presence of deformation and ruptures under loading. In some cases, implants designed and manufactured based on the standards of the ISO or ASTM, which target Europeans and Americans, do not fit the smaller Japanese physical constitution. To design and manufacture prostheses fitting Asians including Japanese, Chinese, and Koreans, it is necessary to evaluate the strength at the stress or strain, which can be scientifically and relatively compared or examined. However, in experimental methods, the use of sensors such as a strain gauge can measure only the surface part where the sensors are set. Thus, we cannot know the strain of an overall implant, and furthermore, it is difficult to obtain the stress distribution inside implants. Therefore, the use of computer simulation, including the FEM analysis, enables us to relatively easily obtain equivalence to an object to be analyzed, to accurately grasp stress distribution in an overall object, and to examine effectively and in detail the effect of each design factor such as shapes and material characteristics.

The ASTM has recently increased movements toward the incorporation of the FEM analysis to its standards. The ASTM/Technical Committee F04 on Medical and Surgical Materials and Devices, which handles medical devices, has started to discuss drafts of new standards related to simulation in the subcommittee on computer-assisted orthopedic surgical systems and in subcommittee F04.22 on arthroplasty. A new direction has been shown to actively incorporate the evaluation of simulation to the approval of medical devices, for example, people in relation to the Food and Drug Administration (FDA) serve as a chairperson of these

subcommittees. Fatigue failure due to repeated dynamic loading on implants is a problem occurring after a long-term postoperative period. Fatigue strength will be also greatly affected because of the change of fixed conditions of implants due to bone remodeling. Although only the experimental evaluation method has been standardized for fatigue strength, it takes a long time for experience and costs more due to issues of reproducibility and re-evaluation associated with the changing of shapes.

If an evaluation technology of fatigue strength using computer simulation is established, we will be able to not only solve such problems but also propose the optimum shape with excellent long-term durability by examining design parameters affecting fatigue strength from the simulation under various conditions.

An example of fatigue strength estimation is a method using the fatigue strength index T (Goodman method). Although it is probably useful to estimate fatigue strength based on simulation, the correlation should be demonstrated by tests in real devices on estimation. An evaluation using the fatigue strength evaluation index T value (see the formula below) on conducting both the fatigue strength test provided in the ISO (ISO 7206-4) and its simulation (using S-N curve of the material) showed a result of good correlation between the experiments and analyses (evaluation index T – fatigue cycle number N).

$$T = \frac{\sigma_{1max}/_2}{\sigma_E};\ \sigma_E = \frac{\sigma_u \cdot \sigma_f}{\sigma_u + \sigma_f}$$

σ_{1max}: maximum primary principal stress (tensile strength) obtained in the FEM analysis

σ_u: rupture strength of the material (experimental value)

σ_f: fatigue strength of the material (experimental value)

The FDA draft guidance instructs showing the type of algorithm of fatigue life estimation, including the Soderberg method, in addition to the above method.

4. Points to consider for the application of numerical analysis to the static mechanical analysis of orthopedic implants

Here we state technical points to consider for the application of numerical analysis to the static analysis of mechanical strength. We will show items necessary for validation, with the handling of issues such as change in material constants used in the analysis, comparison with tests in real devices, and new products.

4-1 Models used for the analysis and volume ratio and mesh division number in real objects

As the element breakdown number changes, the model volume also changes. A rough element breakdown may result in a smaller sectional shape compared with a real object and a greater stress compared with that calculated in a model of a smaller element breakdown. The element breakdown number to sufficiently evaluate the stress status in a stress concentration part is necessary.

If you make the change for an increase/decrease of mesh size or breakdown number centering on the surroundings of a site where a large stress related to strength evaluation occurs, you must check that the site and stress level can be stably obtained similarly. This can prevent you from overlooking errors caused by the FEM modeling of the real object.

4-2 Checking element attributes

Finite elements are classified into low-order elements (primary elements), high-order elements (secondary elements), etc. according to the difference in the number of nodal points comprising the elements. The primary elements show worse convergence than the secondary elements when the elements are fragmented and stress is converged. In the fragmented, secondary elements, the stress may be higher at the part where the outline suddenly changes (neck and ball junction for a joint prosthesis). (This is the opposite of one that shows higher stress than that calculated in a model of smaller element fragmentation.) It is necessary to check convergence by performing a similar analysis in the high-order elements when using low-order elements.

4-3 Factors caused by the difference of element formulation: completely integral elements and reduced integral elements

Some analysis software packages that are commercially available allow us to select various analysis methods that fit to applicable problems. We should advance the analysis in consideration of the properties of these software packages. We should consider the following points:

(1) In the primary elements completely integrated, “rigidity is evaluated to be more rigid than the true value” in the bending problem (shear locking). This is because of the inclusion of shear strain against bending that does not physically exist in the element formulation. Reduced integral elements (non-conformable elements) are the element formulations to relieve shear locking, which are used for bending-dominant problems such as the loading test of a hip prosthesis.
(2) In software packages with a highly general purpose, we can specify either complete integral, reduced integral, or selective reduced integral elements when analyzing. However, we should note that the handling is different between software packages and their versions when using them in default values.
(3) Some software packages focusing on dynamic analysis treat only reduced integral elements.
(4) Some software packages bundled in (added on) CAS software limit the number of element preparations or cannot treat reduced integral elements.

It is not easy to show the reliability of numerical analysis. It will be better to attach the results of benchmark tests (Note 4) with known correct answers recommended by an academic society or to show the convergence of solutions when different loading conditions or mesh divisions are given.

Note 4 For example, The Standard NAFEMES Benchmarks, The International Association for the Engineering Analysis Community.

5. Ideas on the use of numerical analysis for the strength evaluation of orthopedic implants

5-1 Conditions to utilize numerical analysis for the strength evaluation of orthopedic implant devices

The following should be considered based on the discussion in subchapter 3-4 above:

(1) The mechanical behavior of the implant material to be analyzed should be analyzed within the range of minor strain and minor deformation.
(2) In principle, substances to be analyzed should be the ones that behave as linear elastic bodies in a mechanical behavior. Irreversible non-linear deformation shown in subchapter 3-1 (2) and macroscopic breaking shown in subchapter 3-1 (3) should be excluded from the analysis.

(3) For resin materials, etc., numerical analysis can be applied if such materials sufficiently represent the characteristics of deformation, strength, and temperature mathematically and can be treated as linear elastic bodies.
(4) Physical property parameters to be used should be material parameters that reflect actual manufacturing and processing conditions (Note 5) such as surface treatment and structure.
(5) Boundary conditions and loading conditions should be set in sufficient consideration of actual use conditions.

Note 5 Note that there are some cases in which the dependence of physical property parameters on factors such as environmental temperature and moisture (water amount) should be considered.

Currently, it is appropriate that the application of numerical analysis for phenomena meeting the above conditions should be limited to a certain range of the strength evaluation of orthopedic implant devices. For devices not meeting the above conditions, such as those with complicated breaking behaviors on the interface of composite materials and those for which complicated behaviors including displacement between parts in addition to material deformation should be considered, as a result of combined components, numerical analysis results should be utilized, in principle, in combination with the results of evaluation in real devices to evaluate the strength. (For example, the allowable stress should be estimated in a combination of experimental results with numerical analysis results; the working stress *in vivo* should be estimated by utilizing experimental and numerical analysis results to explain that the stress occurring in the implant remains within a sufficiently allowable range.)

We excluded material behaviors mentioned in subchapter 3-1 (2) and (3) because they are currently considered to be difficult to sufficiently validate analysis results. However, numerical analysis is expected to be applied to device evaluation in this field in the future, associated with the progress of numerical analysis and the accumulation of scientific knowledge on related material behaviors.

5-2 Examples of the application of numerical analysis to the strength evaluation of orthopedic implant devices

Under limited conditions, numerical analysis results can be applied, as a substitute of the results of evaluation in real devices, to the strength evaluation of implant devices within the scope of the same application purpose. Taking into account the ambiguity in

the identification of loading conditions under implantation *in vivo* and no obtained quantitative data on allowable stress *in vivo*, currently, the following utilizations may be considered from the viewpoints of the preparation of evaluation data for the application of specific orthopedic implant products and the handling of data for review.

5-2-1 Strength evaluation of products with the same application purpose and with changed dimensions and shapes of approved products

Under the following conditions, if, as compared with the maximum stress of reference products calculated by numerical analysis, the stress value of a product to be applied in the worst case is equivalent to or smaller when a similar numerical analysis is performed, strength analysis results by the numerical analysis can be used as data demonstrating strength performance.

(1) Identical materials and manufacturing processes,
(2) Having basic material characteristic data on the material and applicability of numerical analysis (if there are data published or identified by a standard measurement method, such data should be used for numerical analysis),
(3) Presence of tests results in real reference products (no breaking is confirmed under an appropriate condition), and
(4) No malfunctions associated with mechanical breaking such as damage and fatigue failure of reference products in clinical use.

5-2-2 Strength evaluation of orthopedic implants with the same application purpose and with changed materials or manufacturing process of approved products

The maximum stress calculated by numerical analysis in response to experiments in real devices correspond to the worst case conducted under the following conditions should be handled as the reference value of allowable stress. If the stress calculated by numerical analysis for products with new shapes such as size variations is equal to or less than the reference value, strength analysis results by numerical analysis can be used as data demonstrating strength performance.

(1) Having basic material characteristic data on the material and applicability of numerical analysis (if there are data published or identified by a standard measurement method, such data should be used for numerical analysis),
(2) Evidence, including the worst case, of test conditions in real devices in numerical analysis using the strength data of a standard test piece, and

(3) Presence of test results of tests in real products for application for approval under experimental conditions corresponding to the worst case above (no breaking is confirmed under the experimental condition).

5-3 Utilization of data collected in post-marketing surveillance

Although loading conditions *in vivo* can be estimated including certain ambiguities, it is difficult to strictly identify conditions. It is, therefore, important to analyze data on malfunctions such as damage reported in the post-marketing surveillance of products. If there are not only reports on events of the presence of damage but also information on damaged sites and data in situation where malfunctions occurred, based on this information, we can collect data on what mechanical load was added to implants during the breaking process, the most critical strength expected in designing, and the validity of allowable stress. These data are desired to be collected with a registry. These will be evidence for the validity of the most critical strength, design stress, and allowable stress to be set, which may lead to the improvement of the reliability of strength evaluation by numerical analysis. As a result, we can strengthen the effectiveness of product development by strength evaluation by numerical analysis, instead of that in real devices, and the evidence of utilization of obtained data as data for application for approval. This is considered to contribute to the effectiveness of development.

6. Conclusion

As mentioned above, this subcommittee focused on manufacturing-related evaluation for the strength evaluation of orthopedic implants and decided to save the evaluation of the changes of implants *in vivo* and changes in a living body for another time.

On that basis, first, we began to mathematically specify the scope of deformation and materials that can by analyzed by numerical analysis. We discussed the applicable range, for example, whether material characteristics can be mathematically represented as those of “linear elastic bodies” for individual materials and whether ruptures and plastic deformation that cannot be mathematically represented are included. We put in order concepts such as the most critical strength, allowable stress, and design stress, as well as the ideas of safety factors for use variations and life estimation based on static strength analysis.

For actual evaluation, we also discussed ideas on the use of numerical analysis for materials that have been used before and those that have not, and on that, the tests in real devices should be performed with the extraction of the worst case using numerical analysis. Furthermore, we examined the availability of the data of a test piece.

Because the progress of numerical analysis is significant, it is desired that the expansion of the application of numerical analysis will be discussed, with reference to this report, in the field of medical devices other than orthopedic implants in the future.