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Practical Guide:

Literature-based approach for pre-clinical mechanical testing of spinal implants

Contents

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Introduction

Implants are critical for treating spinal issues, but their failure can lead to patient suffering and high economic costs. Effective pre-clinical mechanical testing is essential to predict and prevent implant failures. However, traditional testing lacks specific regulations, leading to inconsistent strategies. A literature-based approach provides a structured, efficient path from research to test result interpretation, focusing on real-life conditions impacting spinal implants. This approach emphasises aligning tests with actual in-vivo loads, which can enhance safety insights and potentially eliminate the need for comparative implants. This guide outlines how to implement a literature-based approach to optimise spinal implant testing.

Spinal implant failures and testing needs

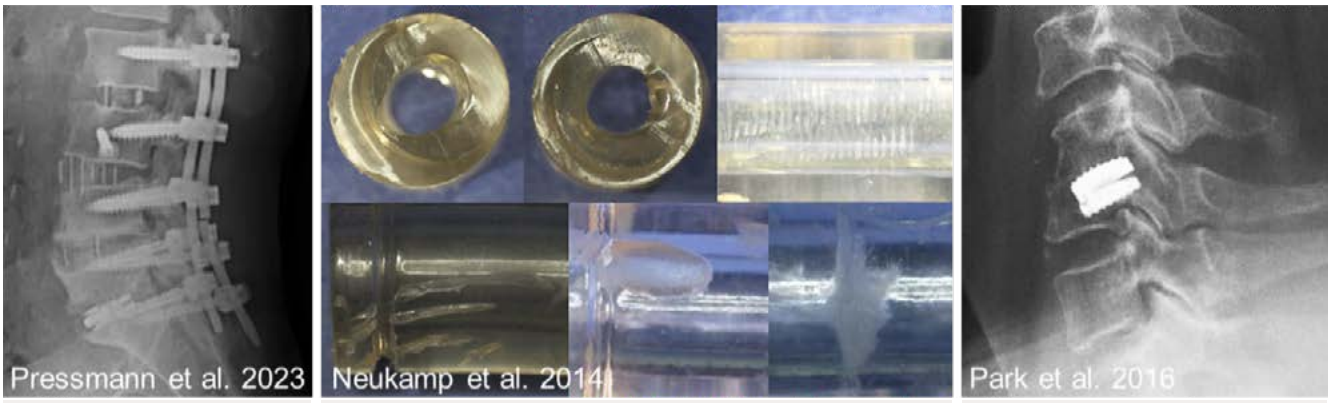
Implant failure has a significant human and economic impact. Spinal implants can fail for various reasons, especially in regions near critical structures like the spinal cord. Depending on factors such as the type of implant or the spinal area, the reoperation rates due to hardware failure vary between less than 0.5% to more than 60% (Table A, Table B).

Treatment	Complication rates cervical spine
Cervical spine surgery in general (Patel et al. 2023[1])	• Reoperation rate 1.24% (30 days after surgery) and 3.30% (90 days after surgery) • Out of those, 4% (30 days) and 6% (90 days) because of hardware failure
Cervical disc replacement (Park et al. 2016[2])	• Subsidence rate of 29% and osteolysis rate around the implant of 14%.

Tab. A Representative implant failure rates for cervical spine surgery as reported in literature.

Treatment	Complication rates lumbar spine
Non-segmental posterior lumbar fusion (Robison et al. 2023[3])	• Hardware failure rate 2.7% and the revision rate was 4.1% (out of 108'137 patients)
Lumbar deformity correction (Pressman et al. 2023a[4])	• 2.6 % hardware failures (mean follow-up of 1'182 days)
Dynamic pedicle screw system (Dynesys) (Chiu et al. 2011[5])	• Case report of a patient who experienced pedicle screw breakage
Dynamic pedicle screw system (Dynesys) (Neukamp et al. 2015[6])	• Polymer wear debris and an associated foreign-body macrophage response in several cases
Two different dynamic fixators (Oikonomidis et al. 2019[7])	• Hardware failure rate 11% and 64%
Charite disc prosthesis (van Ooij et al. 2007[8])	• Inflammatory reaction in the periprosthetic fibrous tissue in 5 out of 5 cases
Lumbar nucleus replacement devices (Pimenta et al. 2012[9])	• Retrieval incidence 48.8% (9 years after surgery) • Main causes: significant loss of disk height at the operated level, displacement, silicone inside the spinal canal, migration

Tab. B Representative implant failure rates for lumbar spine surgery as reported in literature.



Spinal deformity correction: rod breakage.

Motion preserving extradiscal implants: wear.

Artificial disc replacement: subsidence and retropulsion

Fig. 1 Examples of failed implants.

High reoperation rates due to failures, such as rod breakage or subsidence of intervertebral implants, show a need for targeted testing to identify and reduce risks early (Figure 1). Two common testing approaches exist:

- **Standard methods:**
  Advantages: Uses established, standardised tests with possible benchmark data for comparisons.
  Disadvantages: Limited relevance to in-vivo conditions; may miss risks specific to novel implants.
- **Literature-based approach:**
  Advantages: Tailored to real-world in-vivo loads, improving relevance and predictive accuracy.
  Disadvantages: Relies on scientific literature which may have gaps; can be overly detailed for standard implants.

A **combined approach** leverages the benefits of both while mitigating their drawbacks.

Advantages: Reflects in-vivo loads for tailored risk analysis and realistic testing. Utilises standardised methods and benchmark data where possible, ensuring compliance and efficiency. Provides flexibility to adjust test standards to better fit novel designs.
Disadvantages: For standard implants, this approach may still be more detailed than necessary, increasing time and cost.

Whatever route is chosen, an appropriate justification is required. For new or novel implants, literature-based testing is often better suited to predict in-use behaviour.

This approach allows tests to focus on relevant risk areas and eliminate unnecessary tests.

Finite element analysis (FEA) or any other numerical simulation method can support mechanical testing in complementary area such as the derivation of the worst-case-sizes and designs. However, simulation does not replace mechanical testing in most key areas such as fatigue, wear, or corrosion testing.

All the above approaches, if thoroughly applied, have the potential to deliver a full chain of argument for the implant's mechanical safety. The choice of which one to use is a case-by-case decision.

Conducting a literature search

To conduct a systematic literature search and create a strong evidence base for testing, the following steps should be considered:

- **Search objectives:** Identify failure rates, understand functional testing methods, and review standard testing practices.
- **Search strategy:** Use medical and scientific databases (e.g., PubMed, Scopus) with defined keywords and exclusion criteria to retrieve relevant data on spinal implants.
- **Data filtering:** Select studies based on criteria (language, study relevance, etc.) to ensure only pertinent data are included.

1.	Based on the titles and abstracts of all search results, those publications (favourable and unfavourable) that do not meet the exclusion criteria are selected.
2.	After a cross-check for duplicates, the full text of these potentially relevant publications is screened to select the most appropriate articles.
3.	These are passed over for analysis.
4.	Literature cited in the relevant publications are also screened and the whole history summarised in the search statistics.

In a recently published joint paper (JOR Spine. 2024;7:e70026)[10], three structured literature searches according to MEDDEV 2.7.1 rev 4 were carried out to objectively illustrate the scientific rationale behind the literature-based approach to mechanical implant safety. This risk and literature-based approach includes the following steps:

1. **Risk analysis and design input and output**
   A risk analysis based on the ISO 14971 standard is required to identify and evaluate the risks that are associated with the use of an implant. According to the literature search, the following points are among those that should be considered when conducting a risk analysis:
   - Length and composition of a spinal construct can influence the risk of failure.
   - Degree of stiffness of a spinal implant should be addressed regarding the risk of failure at the screw-bone anchorage.
   - Any unfavourable biomechanical environment (incorrect size selection, incorrect placement, etc.) should be considered.
   - Use-time and lifetime in the body should be acknowledged (e.g., corrosion, material aging, fatigue).

2. **In vivo loading of the implant**
   Gather data on in-vivo loads to understand the forces an implant will experience:
   - Investigate load patterns by spinal region, load sharing between implants and bones, and impact of human factors (e.g., surgical technique). Surgeons' procedural preferences can affect implant positioning and stability, impacting mechanical performance. Use literature to build a profile of in-vivo loads relevant to the specific implant and intended anatomical placement (Figure 2).

Fig. 2 Step 2 of the literature-based approach to prove the mechanical safety of a spinal implant: Summary of the in vivo loading of the relevant spinal region and the implant under consideration of the intended use of the implant and human factors.

- When it comes to the mechanical safety of implants, human factors are gaining attention. However, this trend is not yet adequately reflected by the scientific literature. There are only few human factors studies published that relate to the mechanical safety of spinal implants.

3. Test plan

Once the in vivo loading is known from step 2, the test plan can be established. This is the core-document of the risk and literature-based approach. It describes all mechanical tests that are to be carried out.

When drawing up the test plan, FEA is a well-established tool for the derivation of the worst-case sizes and geometries for testing – especially in cases, where a theoretical argumentation reaches its limits. In contrast, FEA is not used as a substitute for physical testing – especially not in cases where fatigue, wear, 3D-printed porous structures, or coated materials are of interest.

In summary, the following points need to be considered during preclinical standard testing:

- Standards do not necessarily represent a reasonable worst-case. They may have to be modified to meet the requirements of a specific implant.
- Standards do not always prescribe all boundary conditions in detail. Wherever there is room for variation well-founded decisions must be made and documented.

In addition to the above points, there is often debate about the sample size. It is therefore recommended to find arguments in favour of each selected sample size – even in cases where recommendations are made in the test standards. Other standards or draft standards from different testing areas may be used as a theoretical background, such as ASTM E122[11] and WK69860[12]. In addition, ensure the test plan is grounded in real-life use scenarios, which can improve predictive reliability.

4. Acceptance criteria

Acceptance criteria are required for each test described in the test plan. Not all standardised test methods include acceptance criteria. For novel designs or innovative clinical claims, current established acceptance criteria in standard testing may not be appropriate. Hence, if the literature-based approach is followed, and the scientific literature database already exists, the derivation of a reasonable acceptance criteria is straight forward[5]

One of the advantages of using comparative tests on predicate devices is that they allow for direct comparison of test results to a clinically proven device, providing a straightforward benchmark. However, there are also disadvantages. Predicate devices are often unavailable for novel implants, and differences in design, materials, or manufacturing processes may limit comparability.

Additionally, there is a risk of creating oversized implants if the predicate device outperforms the actual needs. The in-vivo loading approach offers several advantages. The criteria are based on real-world in-vivo loads, making them applicable to both standard and novel implants. However, gaps in the scientific literature may necessitate assumptions, which can reduce precision.

A combined approach leverages the strengths of using information on predicate devices for comparison where available, complemented by in-vivo load data. This helps avoid oversizing and ensures that the criteria are robust and tailored to real-world performance.

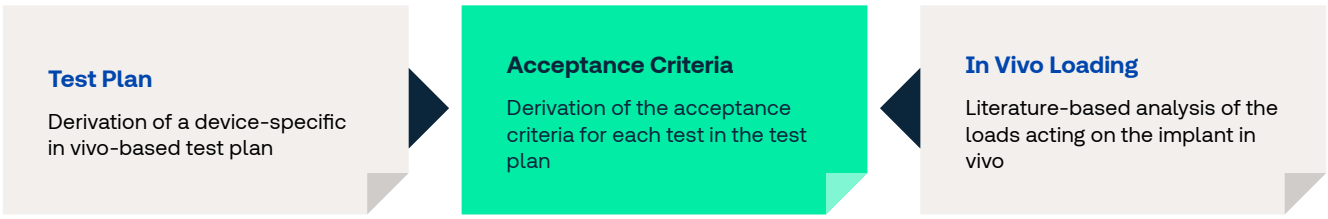


Fig. 3 Step 4 of the literature-based approach to prove the mechanical safety of a spinal implant: Derivation of acceptance criteria for each single test described in the test plan. This derivation is based on the in vivo loading as summarised in step 1.

5. Worst case sizes and designs

The worst-case sizes and designs of the implant depend on the device portfolio and should be defined for each single test separately[6]. It is important to consider all implant-specific features that could have an influence on its stability under the respective loading conditions. This argumentation may be done based on numerical simulation (FEA) and/or based on a geometry- and material-related justification.

Fig. 4 Step 5 of the literature-based approach to prove the mechanical safety of a spinal implant: Selection of the worst-case sizes and designs of the implant for each single test described in the test plan

6. Mechanical Testing

As soon as the above documentation is finalised, mechanical testing can be conducted as defined in the test plan. Care should be taken to justify each single test parameter. Also, verification and validation of the procedure should be provided before application. In contrast to worst-case derivation, FEA is less common to replace testing. Especially for fatigue and wear testing.

7. Assessment of the results

During the assessment the results are compared to the acceptance criteria[7]. If the comparison results in a 'pass', the assessment is completed. In cases where the acceptance criteria are not met, further actions must be taken. For example, this might include re-interpretation of the test results, optimisation of the implant design, restriction of its use to a certain patient population, or an update of the performance claims.In cases where the implant design must be changed, to check whether any revision is required the literature or risk-based approach must be re-started from step 1.

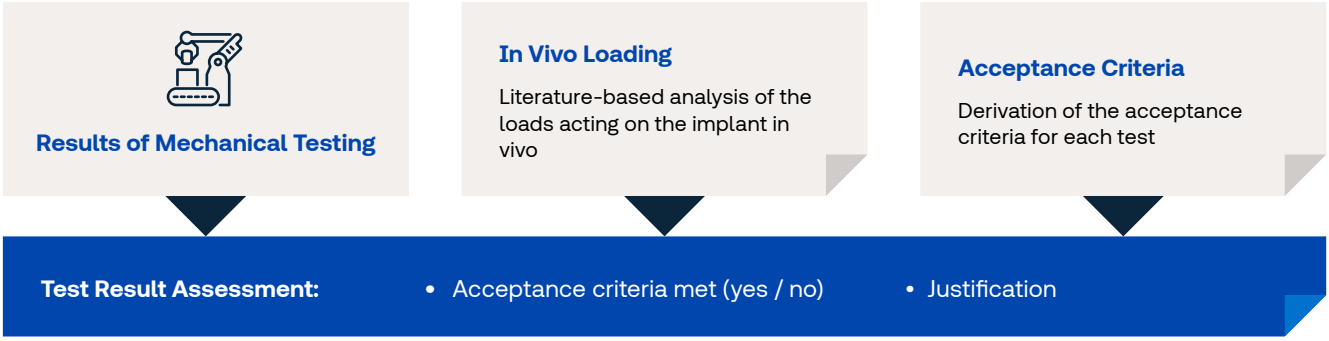


Fig. 5 Step 7 of the literature-based approach to prove the mechanical safety of a spinal implant: Assessment of the test results

Discussion

The literature-based testing approach offers significant benefits for novel implants, helping to:

- Enhance testing efficiency: Targeted testing reduces unnecessary procedures, aligning tests with realistic in-vivo forces.
- Improve predictive accuracy: Real-world load data inform testing and acceptance criteria, supporting a robust safety profile.
- Support regulatory compliance: Addresses General Safety and Performance Requirements (GSPRs) under EU MDR Annex I, streamlining approval processes for market entry.

This method aligns scientific findings with regulatory standards, bridging the gap between lab testing and real-life application. Compared to the conventional approach that uses standard test methods and predicate devices to establish the acceptance criteria, the risk and literature-based approach demonstrates its strengths, especially with novel implants. But also in the case of standard implants, the literature-based approach can help to focus on the real risks. If combined with predicate device testing this approach covers both flexibility and efficiency.

In principle, the scientific literature is the best database that we can use for derivation of an in vivo based mechanical test plan. However, there are certain gaps in literature. For a full chain of arguments, it is important to bridge these gaps using an additional rationale. Mostly, a literature-based rationale helps to bridge the gap.

As soon as a full chain of arguments is successfully built up, this procedure allows for individual testing, individual test result interpretation and, which is most important, for addressing the real loading that is expected to act on the implant in vivo. This has the potential to further reduce the risk of implant failure.

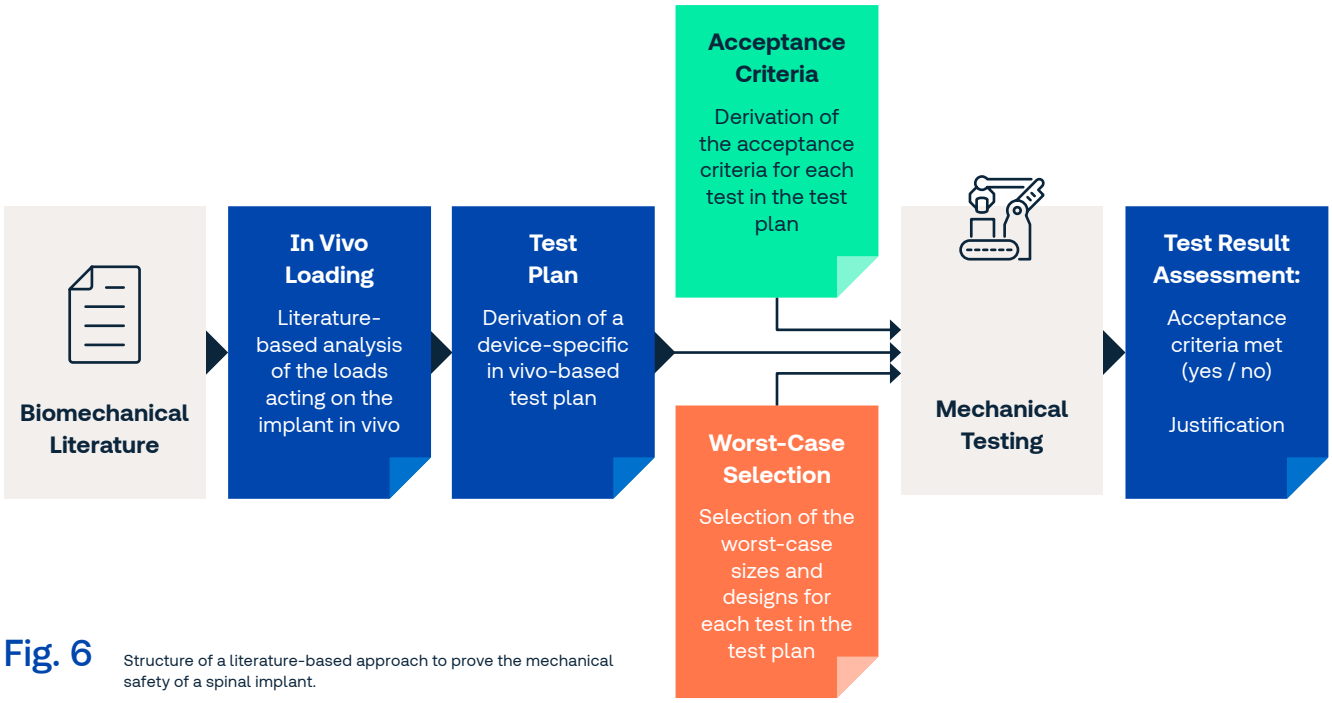


Fig. 6 Structure of a literature-based approach to prove the mechanical safety of a spinal implant.

This guide illustrates how a literature-based approach optimises spinal implant testing, from literature review through to testing and result analysis, making it a valuable strategy for enhancing patient safety, supporting compliance, and reducing failure risks.

In conclusion, the literature or risk-based approach to pre-clinical mechanical testing offers the potential to create a coherent and targeted chain of arguments, from literature review through testing to the interpretation of test results. This methodology can significantly enhance testing efficiency, reduce the risk of failure, and ultimately prevent unnecessary patient suffering and healthcare costs.

Important:

While this approach mainly focuses on mechanical testing, other factors like biocompatibility and MRI compatibility are essential, particularly for implants with novel materials. Materials such as PEEK, titanium, and emerging bioactive materials (e.g., bioactive glass) each require additional evaluations to ensure long-term safety and performance in the body.

TÜV SÜD as an independent testing provider can support:

Fig. 7 Mechanical testing must be accompanied by safety considerations in various other areas (representative topics). TÜV SÜD can help you.

Glossary of acronyms

FEA	Finite element analysis
GSPRs	General Safety and Performance Requirements
MDR	EU Medical Device Regulation

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