Clinical outcomes and implant-related complications after pedicle-anchored dynamic or hybrid lumbar spine stabilization: a systematic review

Marion Prud’homme 1, Carlos Barrios 2, Philippe Rouch 1, Yann Philippe Charles 3, Jean-Paul Steib 3, Wafa Skalli 1

1 Laboratoire de Biomécanique, Arts et Métiers ParisTech, Paris, France
2 Institute for Research on Musculoskeletal Disorders, Valencia Catholic University, Valencia, Spain
3 Department of Spine Surgery, University Hospital of Strasbourg, France
**Objetives**

- To give a global overview of clinical outcomes of Pedicle-based Dynamic devices
  - VAS, Oswestry DI, patient satisfaction
- To analyse the specific device related complications focussing:
  - Implant failures, Adjacent segment degeneration and Revision surgery
**Main inclusion criteria**

- Only **Pedicle-based** devices used for **dynamic-and topping-off** stabilization
- Clinical studies, **mean Follow-up ≥ 12 months**
- Outcome information: VAS, ODI, Complications (breakage, loosening, ASD, …)
Clinical studies: 27 (58.6%) published in 2010-2012

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>(% of Patients)</th>
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<tbody>
<tr>
<td>Prospective</td>
<td>28%</td>
</tr>
<tr>
<td>Prospective comparative</td>
<td>12%</td>
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<tr>
<td>Retrospective</td>
<td>23%</td>
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<tr>
<td>Retrospective consecutive</td>
<td>37%</td>
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Total: 2023 patients
Average: 47 patients/study

Patients reported
- Mean
- Total
Dynamic versus Hybrid Stabilization

Hybrid stabilization
Fusion + Topping-off construct

- Patients: 145 (7%)
  - 1015 (93%)

- Studies: 7 (15%)
  - 39 (85%)

Pure dynamic stabilization
Only flexible instrumentation
Dynamic Stabilization of the Lumbar Spine

Dynasis®
Ligamento + PET
29 Estudios (63%)

Device type:
- Accuflex
- Agile
- Bioflex
- Cosmic
- Dream Elastic
- Dynesys
- Flex+
- Isobar
- Isolock
- Nflex
- Safinaze
- Twinflex

Device system:
- Metallic core + PCU
- Metallic spring
- Hinged screws
- Hinged rod
- Ligament +PCU

26
1
1
1
1
1
1
2
3
4

63%
9%
11%
11%
6%
Patients satisfaction
At 44-month mean follow-up: 83.4% of 635 patients interviewed would return to undergo surgery knowing their current outcome.
Complication related to the implants

Dynamic Implant Failures

- Rod Breakage
- Screw Breakage
- Screw Loosening

Implant Failure
(<4-year Follow-up)

- Dynamic
- Hybrid

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<thead>
<tr>
<th></th>
<th>Dynamic</th>
<th>Hybrid</th>
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<tbody>
<tr>
<td>Rod Breakage</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Screw Breakage</td>
<td>1.2%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Screw Loosening</td>
<td>4.5%</td>
<td>5.8%</td>
</tr>
</tbody>
</table>

Follow-up (years):
- 2
- 3
- 4
- 5

Dynamic Implant Failures distribution:
- Rod Breakage: 4.2%, 4.6%, 9.3%, 21.9%
- Screw Breakage: 4.2%, 4.6%, 9.3%, 21.9%
- Screw Loosening: 4.2%, 4.6%, 9.3%, 21.9%
Clinical Complications

Revision Surgery and ASD
(4-year Follow-up)

Revision Surgery and ASD
Revision Surgery ASD

Revision Surgery and Adjacent Segment Degeneration *versus* length of follow-up

Revision Surgeries in Lumbar Fusion = 20% a los 5 años
Adjacent Disc Disease = 22% a los 5 años

Clinical Complications

Revision Surgery and ASD

Ligament + PCU
Metallic Spring
Hinged Screw
Metallic core + PCU
Hinged Rod
Hybrid Construct

Revision Surgery ASD

Revision Surgery and ASD

Revision Surgery ASD
Lack of information about the key parameters:

**Design** (axial and bending stiffness [Schmidt et al. 2009] / shear resistance [Hoff et al. 2012])

**Surgical technique** (Pre-constraining, destabilization)

**Balance** Balance → muscular forces [Legay et al. 2008]
  - Sagittal balance changes → ASD [Kumar et al. 2001]
  - Difficulty to achieve the right lordosis → Posterior structures overloading

Only 1 study dealing with pelvic parameters [Ricart et al. 2008]

- **Overview 2023 patients /47 studies**
  - → **High variability** (complication rates)
- Clinical results non inferior to literature reports about fusion
  - → Lack of **Long-term** comparative studies (ASD)
- Still a need of **Postural balance parameters**
  - → Patient selection
Pedicle based dynamic stabilization devices show clinical results similar to fusion and no clear evidence of advantages for the protection of adjacent segment degeneration through this mid-term review.

Technical failures are not only design related but also linked with patient specificity.

Relationships between sagittal balance and surgery outcomes are still rarely reported but an in-depth biomechanical analysis would allow a refinement of surgical strategy.

Dynamic stabilization might display advantages in selected indications such as moderate disc or facet degeneration and beginning instability.
Disclosure information

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Author:
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Yann Philippe Charles      Nothing to declare
Jean-Paul Steib             Nothing to declare
Wafa Skalli                 Nothing to declare