UNID™ Rods

Patient-Specific Rods show a reduction in rod breakage incidence

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OBJECTIVE

To describe and analyze rod fracture incidence observed using patient-specific rods

Adult Spinal Deformity (ASD) is becoming increasingly prevalent as the population ages. Its negative impact on quality of life often necessitates surgical intervention, especially for disabling or progressive deformities. Advances in instrumentation, surgical techniques, and surgical management over the last decades have enabled improving rates of curve correction, patient satisfaction and functional outcomes. Technical improvements have also eased the correction of more complex deformities including those in frail or older patients.

However, the incidence of associated complications is still relatively high, possibly attributable in part to the broadening of the target population. Perioperative morbidity includes an approximate 13% risk of pseudarthrosis and a greater than 40% incidence of perioperative adverse events [1]. Within 2 years postoperatively, the overall revision rate can reach up to 16.5% [2]. Revisions lead to additional hospital charges, supplemental risks for infection and may have an impact on final treatment success.

Implant-related complications are predominant and special care should be taken to anticipate and avoid them [2]. Overall rod breakage incidence is reported as high as 14.9% in patients following ASD surgery [3-6]. When a pedicle subtraction osteotomy (PSO) is performed, the rod fracture rate increases to 22% and in these cases, 90% of failures are found to occur at, or adjacent to, the PSO level [3-5]. Furthermore, the time to failure is seen to occur within 10 months after surgery [3]. Risk factors for rod breakage include rod diameter and material, excessive rod contouring (>60%) and notches introduced by rod-benders during the contouring process, or through connections with other implants including screws, dominos and hooks [5,7-8].

The recent development of patient-specific pre-bent rods (UNiD™ Rods) planned with Surgimap software (Nemaris Inc, New York, NY) offers a solution that may reduce risk factors listed above. In addition to serving as an intraoperative tool to achieve precise and pre-operatively planned deformity correction tailored to each patient’s parameters and surgeons strategy, the rods are manufactured with a smooth curve compared to those bent with a French-bender. The industrially pre-contoured rods are delivered ready to implant without additional contouring required in the operating room, reducing or...
eliminating surgical time used to manually bend rods and preventing notches. The hypothesis was that this new family of implants reduces the rod breakage rate and associated surgical revisions. This paper aims to quantify and describe patient-specific rod failures compared to conventional rods.

**MATERIALS AND METHODS**

A prospective anonymized adverse event database was generated through three pathways. The first is a European clinical trial (NCT02926404), the second is the UNiD™ HUB, a platform which allows surgeons to send anonymized postoperative X-rays to the UNiD™ LAB for assessment of radiological results and comparison to preoperative and planned sagittal parameters. The last is the MEDICREA® post-market survey which collects all client complaints and adverse events reported on MEDICREA®’s products.

**RESULTS**

**COHORT DESCRIPTION**

UNiD™ Rods were first implanted in September 2013 in Europe and in November 2014 in the United States. Between September 2013 and the end of June 2017, 1515 surgeries using UNiD™ Rods were performed worldwide, of which 759 occurred in the United States and 756 occurred outside of the United States, mainly in France. Among the 1515 surgeries using UNiD™ Rods, 733 were performed more than 1 year ago and 280 more than 2 years ago.

These 1515 surgeries included at least 1031 (68%) adult cases (3% of patients’ age are not documented). Among adult spinal surgeries using UNiD™ Rods, 889 (86%) were implanted for ASD (>4 levels) and involved a mean of 10 levels instrumented. The cohort analyzed in the current paper includes 453 ASD patients implanted for more than 1 year.

**ROD Fracture**

Considering only ASD cases implanted UNiD™ Rods for more than 1 year, 10 patients reported 11 rod breakages (2.2%). One patient who was unwilling to undergo previously planned supplemental anterior fixation, experienced a rod breakage at 3 months follow-up. The patient was revised, but again declined the supplemental anterior fixation and experienced a new rod breakage 12 months after the revision. The patient was revised a second time and finally accepted the additional anterior support.

The 10 patients who developed failure had a mean of 12 levels instrumented. In terms of 3-column osteotomies, 2 underwent a vertebral corpectomy (1 double-level at L3L4 and 1 single-level at L2), and 6 underwent one PSO (3 at L3; 2 at L2; 1 at L4).

Regarding rod material, 2 surgeries were performed with Cobalt Chromium 5.5 diameter rods, 4 with Cobalt Chromium 6.0 diameter rods, and 5 with Titanium 6.0 diameter rods. To date 10 out of 11 rod failures were revised.

**PEDICLE SUBTRACTION OSTEOTOMIES**

PSOs were performed in 157 ASD surgeries (17.6%) and 127 were performed at more than 1-year ago. Six out of 127 ADS surgeries with PSO had a rod failure, always occurring around the PSO site. Overall, when a PSO was performed, the incidence of rod breakage was 4.7%.

**DISCUSSION**

The use of UNiD™ pre-contoured patient-specific rods in spinal surgeries seems to dramatically reduce rod breakage incidence when compared to incidence rates found in literature. Indeed two independent publications reported an incidence of 9% [4-5].

**Table 1: Description of surgical parameters**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients implanted with UNiD™ Rods at the end of June 2017</td>
<td>1515</td>
</tr>
<tr>
<td>UNiD™ Rod ASD surgeries performed before June 2016</td>
<td>453</td>
</tr>
<tr>
<td>UNiD™ Rod ASD surgeries with PSO performed before June 2016</td>
<td>127</td>
</tr>
<tr>
<td>Total ASD patients having UNiD™ Rod breakages</td>
<td>10 (2.2%)</td>
</tr>
<tr>
<td>Total ASD patients with PSO having UNiD™ Rod breakages</td>
<td>6 (4.7%)</td>
</tr>
</tbody>
</table>
while Hamilton et al. [6] recently reported a 14.9% rod breakage incidence at 2 years follow-up based on data from the International Spine Study Group. When a PSO is performed the rod breakage incidence has been reported as high as 22% [4].

Despite the short follow-up period, the rate of 2.2% rod breakage is encouraging, especially considering surgeons often utilized UNiD™ patient-specific rods in their more complex surgeries. As the technology is recent, adverse events such as rod failure are well reported, even in cases with incidental finding, limiting bias of underestimation.

It is important to note that among the 11 rod failures observed, 3 underwent bending in the operating room which could have weakened the rod by creating notches.

This paper presents several biases and limitations, of which the foremost is a short follow-up period. Other limitations include the lack of control group and the inability to guarantee precise and accurate surgical accounts for all cases and the non-exhaustive collection of all postoperative data.

Nevertheless, the encouraging results found in this study now need to be confirmed over longer-term follow-up. It is expected that incidence will increase with a longer follow-up. However the early findings of this study: 2.2% rod breakage overall and 4.7% in cases where a PSO were performed are promising and well below incidences previously reported [3-6]. Risk factors for rod breakage and subgroup analyses regarding indications and constructs should also be addressed in future studies.

**CONCLUSION**

Rod failures were detected in 2.2% of ASD patients with implanted UNiD™ patients-specific rods and in 4.7% of cases with a PSO performed. When compared to literature, both rates are considerably less and encouraging. This demonstrates that use of pre-operatively planned patient specific rods with an absence of manual rod contouring can have a major impact on rod failure.

**KEY POINTS**

- Rod breakage was detected in 2.2% of patients implanted with patient-specific UNiD™ Rods
- The incidence of UNiD™ Rod breakage when a PSO was performed is 4.7%
- Global incidence of rod fracture with UNiD™ Rods is considerably less than incidence reported in literature
- These promising results should be confirmed over longer follow-up

**REFERENCES**


**UNiD™ Rods**

UNiD™ Rods are a device intended to be used for correction and surgical stabilization of the thoracic, lumbar and sacral spine only. Please read the instructions for use carefully.

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