Non-fusion stabilization of the lumbar spine in the case of degenerative diseases with a dynamic pedicle screw rod

Estabilização dinâmica da coluna lombar no tratamento das doenças degenerativas

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ABSTRACT

Objective: To compare the results of the posterior non-fusion stabilizations and fusion in the treatment of painful degenerative diseases of the lumbar spine. Methods: Cosmic is a dynamic non-fusion pedicle screw rod system for the stabilization of the lumbar vertebral column. The hinged pedicle screw provides for the load being shared between the implant and the vertebral column and allows a high stability in relation to the rotational forces. This report covers the clinical and radiological results of 96 patients with a follow-up of 12 to 24 months. The clinical results were compared with those from 75 patients that had been treated with hinged screws and a conventional posterolateral fusion. In both groups the indications were comparable:

Symptomatic spinal stenosis, discogenic pain, facet syndrome, and post-diskectomy syndrome. Results: In both groups, the Oswestry score and the analogue pain scale showed a good reduction of the symptoms without any significant differences. The perioperative morbidity in the non-fusion group was significantly lower. In the non-fusion group, with 494 screws implanted, two broken screws were found in two patients. In the case of five patients, ten screws with radiological loosening were found. From these seven patients, three again developed symptoms that led to a revision. In the fusion group, three pseudoarthroses with screw fracture were found that were also revised. All implant-related revisions occurred within the first year. Conclusion: The early and medium term results found so far with the cosmic system are very encouraging. Additional long-term observations are necessary.

KEYWORDS: Low back pain; Lumbar vertebrae; Spinal diseases; Spinal fusion

RESUMO

Objetivos: comparação dos resultados do tratamento das afecções degenerativas da coluna lombar pela estabilização posterior com e sem artrodese. Métodos: “Cosmic” é um sistema de haste e parafuso pedicular dinâmico para a estabilização da coluna lombar sem artrodese. O parafuso pedicular articulado faz com que o carregamento mecânico seja dividido entre o implante e a coluna vertebral e permite uma alta estabilidade em relação às forças de rotação. Este trabalho apresenta os resultados clínicos e radiográficos obtidos em 96 pacientes com acompanhamento pós-operatório de 12 a 24 meses. Os resultados clínicos foram comparados aos obtidos em 75 pacientes, tratados com parafusos articulados e a convencional artrodese póstero-lateral. Nos dois grupos, as indicações foram comparáveis: estenose vertebral sintomática, dor discogênica, síndrome facetária, e síndrome pós-discectomia. Resultados: nos dois grupos a escala de Oswestry e a escala analógica da dor mostraram boa melhora da sintomatologia sem diferenças significativas. A morbidade peri-operatória no grupo sem artrodese foi significativamente mais baixa. No grupo sem a artrodese, com 494 parafusos implantados, foram encontrados dois parafusos quebrados em dois pacientes. Em cinco pacientes, dez parafusos com sinais radiográficos de afrouxamento foram identificados. Dos sete pacientes, três desenvolveram a sintomatologia clínica que nos obrigou à revisão operatória. No grupo com artrodese, três pseudoartroses com ruptura dos parafusos foram encontrados, e estes pacientes também foram reoperados. Todas as revisões operatórias relacionadas com problemas do material de implante foram realizadas durante o primeiro ano de pós-operatório. Conclusão: os resultados precoces e em médio prazo obtidos com a utilização do sistema “Cosmic” são encorajadores. Observações adicionais em longo prazo ainda são necessárias.

DESCRITORES: Dor lombar; Vértebras lombares; Doenças da coluna vertebral, Artrodese

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INTRODUCTION

The degeneration of the lumbar motion segment starts with a height loss of the disc caused by a water loss of the nucleus pulposus. The facet joints lose their congruence which may cause a consecutive spondylarthritism. The vertebral column ligaments loose tension so that a structural loosening occurs complete with increased rotation instability2,4. In order to compensate the instability, a hypertrophy of the yellow ligament as well as the facet joints occurs very frequently, which may lead to a reduction of the surface of the cross-section of the central as well as lateral spinal canal. At the same time the motion segment may loose its original position, and scoliosis, flat backs, rotations, and rotation slidings may develop. During the further course of the degeneration, lateral and front spondylophytes up to and including syndesmophytes may form which in its turn may lead to a spontaneous stiffening of the segment.

The complaints depend on the respective stage of the vertebral column degeneration. In the first phase with a reduction of the height of the vertebral disc and loss of the congruence of the facet joints, chronically recurrent lumbalgies may occur that increase under load stress. When the stenosis of the spinal channel increases, additional symptoms may occur in one or both legs with the indications of a claudicatio spinalis. If a spontaneous ankylosis of the segment occurs before a symptomatic spinal channel stenosis occurs, the frequency and intensity of lumbalgies decreases.

The cause of the leg symptoms can be well explained by the compression of the nervous structures caused by a narrow spinal channel or recessus or neuroforamen. As a rule, an adequate decompression of the neural structures leads to good clinical success. The etiology of the lumbalgia is less clear; and, also, the clinical success does not occur in the same measure as the fusion rate of a spondylodesis. What may be assumed to be certain is that the instability in the motion segment caused by the vertebral disc shrinkage is a trigger for the frequency of occurring lumbalgies. Non-physiological movements that only have become possible due to the vertebral disc shrinkage, lead to a shifting of the nucleus pulposus or nucleus pulposus fragments within the vertebral disc, with the vertebral disc itself experiencing an increased in-growth of pain-conducting nerve ends as a result of the degeneration4. This increased innervation of the degenerative vertebral disc is also responsible for the “Memory Pain” in the discography6.

The term “instability” used in this connection has been better defined by Panjabi as a “clinical instability” which leads to a pathological movement capability and leads to pain, deformities, and neurological failures3.

The operative treatment of the symptomatic lumbar vertebral column degeneration so far consisted of stabilising the diseased segment or the diseased segments, and also to correct and adequately decompress the same; always in connection with a spondylodesis. In recent years, the various different forms of the spondylodesis (ALIF, PLIF, TLIF, PLF) were discussed very intensively, as one believed to be able to increase the clinical success rate above all by means of 360 degree fusions.

This could be rejected in a prospective randomized double blind study. The clinical results were independent of the selected fusion form. Complications naturally increased in line with the increased surgical work effort (360 degree fusion). In this study, pseudarthroses did not have any influence on the clinical result5.

A possible disadvantage of the spondylodesis in the treatment of degenerative lumbar vertebral column diseases consists of the increased risk that the degenerative processes in the neighbouring segment accelerates. Following a spondylodesis, 16.5% symptomatic vertebral disc degenerations after five years were expected in the neighbouring segment, and 36.1% after ten years8. Obviously there is a lower risk for spondylodesis without the use of pedicle screw systems10. It must be questioned whether the risk for the adjacent segment increases with the rigidity of the spondylodesis, which would above all concern the currently favoured 360° fusions with cage in combination with a pedicle screw system11-13.

This does not appear to apply to spondylodesis that were carried out for the correction of extended deformities. Thus, even after twenty and more years following a Harrington spondylodesis, low back pain was found in only 13% of cases14.

Why are spondylodesis carried out in the treatment of degenerative lumbar vertebral column diseases?

Until recently, there were few alternatives to a standard spondylodesis. One important reason is that the surgery of the degenerative lumbar vertebral column is a relatively young chapter in the spine surgery. The techniques of correction and fusion, so successful in scoliosis surgery, were transferred to this new area of spine surgery, ever increasing since the early 1980s. An essential task of the spondylodesis consists of protecting the implants used against failure (dislocation, breakage).

When is a correction necessary?

In contrast to the treatment of an adolescent scoliosis, where the correction of the deformity is also the objective of the treatment, there are not very many indications for the correction of the degenerative lumbar vertebral column that actually serve the direct objective of the operation with pain release and restoration of neurological functions.

Positional deformities in the sagittal and frontal planes that in total do not lead to a loss of the body vertical plump line need not be corrected. This concerns most lateral deviations. Therefore, the correction of a degenerative lumbar scoliosis is only necessary in exceptional cases.

The reduction of the vertebral disc always leads also to a flattening of the lumbar vertebral column, which also does not need to be corrected as long as the patient assumes an upright well-balanced posture. True and degenerative olisthesis at an adult age are mostly not progressive. Stabilisation and decompression without correction lead to the objective of the treatment. Therefore, it is not meaningful to transfer the principles of scoliosis surgery non-critically to the surgery of the degenerative lumbar vertebral column.
- **When will it be possible to do without a fusion?**

  The precondition is a dynamic implant, which does not require the protection of a spondylodesis. It must be possible to achieve the treatment objective (pain release, restoration of the neurological function) without correction. The stabilisation does not need to include more than three segments.

- **When is a fusion necessary?**

  When corrections (mostly in the sagittal plane) are necessary in order to treat pain.

- **What properties must a non-fusion implant system have?**

  For the implant system to be able to exist without the protection afforded by a spondylodesis, it must not have any rigid properties. Rigidity means a missing load sharing between the implant system and the anterior vertebral column.

  On the other hand even a non-fusion implant must stabilise the motion segment and control the pathological motion patterns (rotation and translation).

- **How can a dynamic implant be stable at the same time?**

  Dynamic and stability are contradictory properties only when considered superficially.

  In nature and the sphere of engineering, there are numerous examples for stable but non-rigid constructions (trees, suspended bridges). Rigid vertebral column implants were originally developed for fracture surgery in order to enable three-dimensional corrections. Many surgeons believe that only rigid implants lead to a sufficient degree of stability. The cosmic system is a pedicle screw rod system where the head of the screw is connected to the threaded section via a hinged joint. Similar to the hinge on a door, the hinged joint permits motions in one plane only. The screws are inserted at 15 to 25 degrees, converging, relative to the sagittal plane. When the screws have been connected by means of the longitudinal rods, there exists a high degree of stability in relation to the rotational forces, as well as a micromobility in the sagittal plane. As the hold of the screws within the bone is of significant importance here, the screws are electrochemically coated with hydroxyapatite. This furthers the titanium screws to rapidly heal into the bone. For this reason, cosmic is not only used for purely discogenic or facet-joint related pain conditions but also in cases where, additionally, a laminectomy or a facetectomy must be carried out due to a spinal stenosis. Cosmic thus features the properties of a stability prosthesis (Figure 1).

- **For what indications is “cosmic” used?**

  **Symptomatic spinal stenosis:**

  In the case of the claudicatio spinalis, caused by a central or lateral lumbar stenosis, we stabilise the affected segment(s) with cosmic and carry out an adequate conventional decompression (laminotomy, laminectomy, facetectomy) (Figure 2 A, B, C). At first, the patient is placed in a physiological lordotic position.

  **Recurrent disc prolapse:**

  In the case of a second recurrence of a prolapse at the same height and on the same side, a stabilisation with cosmic is performed in addition to the nerve root decompression.

  **In combination with a spondylodesis:**

  If the indication of a spondylodesis exists in a segment, as a considerable instability in the flexion / extension has been proven or if there is a necessity for correction and, in addition, a painful vertebral disc disease in an adjacent segment, then cosmic can be used in one segment in combination with a fusion and in the adjacent segment without fusion.
In the case of a painful adjacent level to a pre-existing spondylodesis:
In particular, when a 360-degree fusion with cage implantation and a rigid posterior pedicle screw system exists, there is the risk of painful adjacent segment degeneration. In this case, the rigid posterior system is removed and the newly diseased segment stabilised with cosmic. The old pedicle holes are filled up with longitudinal matches like bone chips from the spinous process and occupied with cosmic 7mm revision screws (Figure 3 A, B).

Chronic lumbargy in the case of discogenic or facet joint-related pain:
In the case of chronic lumbargy after successless conservative treatment with the existence of an MR-tomography osteochondrosis with vertebral disc dehydration and positive Modic sign we carry out a discography. In the case of a positive memory pain, there is a symptomatic vertebral disc degeneration. If the contrast agent flows through the degenerated vertebral disc, without building up pressure, a memory pain can frequently not be triggered.

In such cases, however, increased segment instability can be assumed. In the case of a temporary pain reduction by facet blocking with 2 ml local anaesthetic each, there is a facet syndrome. In such cases we carry out a posterior stabilisation with cosmic using a paraspinous transmuscular access according to Wiltse (Figure 4 A, B, C, D).

● Contra-indications:
Cosmic without spondylodesis is not used if posture corrections of the vertebral column that are not solely reached by a more favourable position of the patient on the operating table, are carried out. Such a situation exists e.g. in the case of a painful kyphosis of the lumbar vertebral column, where the correction in the sagittal plane significantly contributes to the objective of the treatment. Here, cosmic is used in combination with a spondylodesis. Another example is the progredient, instable true spondylolisthesis in a youth or young adult. In such cases we carry out a partial reposition from dorsal, in combination with a postero-lateral and retroperitoneal front fusion.

● Extended stabilisations longer than three segments:
Cosmic without spondylodesis should not be used for instrumentations longer than three segments. The indications for an extended instrumentation and spondylodesis must be decided very critically in the case of the degenerative lumbar vertebral column. If such a stabilisation cannot be avoided, it must be examined whether there is the option that only part of the segments are treated by fusion and whether the cranial segments can be stabilised by non-fusion techniques.

METHODS
The cosmic pedicle screw is available as a standard 6mm screw with a 4.0 mm internal diameter, and as a 7.0 mm screw revision screw with a 5mm internal diameter.

The head and threaded section are permanently connected as a joint, like a hinge, via a small axis. The thread is self-tapping so that a rule it is possible to do without a first tap. If used in the
sacrum, a bicortical implantation is recommended. Implantation is easier in particular in the case of osteoporotic bones if the thread is first cut. The screw tip is rounded in order to avoid the risk of injury. The material is a titanium alloy, and the threaded section is additionally coated with calcium hydroxyapatite. The rods have an external diameter of 6.2 mm and an internal diameter of 6.0 mm. They feature a thread in order to provide for a rotation stable connection with the screw head that, in its base, also features a thread (Figure 1).

The connection between screw and rod is ensured by a grub screw that is tightened by a definitive force of 6 Nm.

There are closed and open screws that are closed with a cap, after the rod has been placed on the base of the screw head. In the case of monosegmental instrumentations, short straight rods are used. In the case of two- and three-segmental instrumentations, the rods are first bent lordotically. A favourable lordosis is generated by the positioning of the patient. The implantation angle of the screw relative to the sagittal plane is approximately 15 to 20 degrees. This protects the facet joints; longer screws can be used; the risk of a lateral or medial perforation is lower; and, on the other hand, it is avoided that the hinge joints of the screws are located in parallel to one another. With this implantation technique, there exists a micromobility in the sagittal plane (flexion, extension), which avoids a rigid fixation and also any excessive mobility in the sagittal plane. The screws are deeply implanted in the pedicle in order to keep the leverage forces that act on the implants as low as possible. The instrumentation can be effected either via a conventional midline incision with dissection of the muscles across the joints lateral to the bases of the transverse processes. Alternatively, the instrumentation can be effected via a transmuscular access between the multifidus and longissimus of the sacrospinalis muscle, either via two separate paraspinous skin cuts or by means of a midline skin cut with subcutaneous preparation of the muscle gap. This muscle gap is located laterally 4 cm (two finger widths) from the midline. If there is an additional need for decompression, then this can be effected via a limited preparation of the multifidus muscles from the vertebral lamina starting from the midline. The latter procedure is protecting the back muscles and recommended above all in the case of individuals with strong muscles.

The mobilisation of the patient is effected on the 1st post-operative day (transmuscular access) or on the second post-operative day (conventional access) without any external support.

A vacuum drainage is removed on the 1st post-operative day. As an infection prophylaxis, cephalosporin is given once before the skin cut. The thrombosis prophylaxis is carried out with a low molecular heparin up to 3 weeks post-operatively.

From January 2002 to 30 June 2005, 203 patients were operated on. In the case of 96 patients, there is a one year follow-up available, and from this number, there is a subset of 38 patients with a two-year follow-up. Preoperatively, the complaints were documented using the Oswestry-Score and a corresponding pain scale from 0 to 10 (0 = no complaints, 10 = an unbearable pain).

For all patients there is a conventional x-ray image of the lumbar spine a.p. and lateral when standing up, and, for some questions raised, an additional lateral x-ray of the lumbar spine in flexion/extension when lying down. For all patients, a MRI of the lumbar spine is additionally available. The screw position was checked during surgery by means of a C arm in the lateral radiation path, and, on completion of surgery, additionally in the a.p. radiation path. Before discharge from hospital, another x-ray check of the lumbar spine in an upright position was carried out a.p. and laterally. After 3 months, 12 months, and 24 months, clinical checks were carried out in accordance with the Oswestry-Score and the corresponding pain scale, and, in addition, a radiological check of the lumbar spine a.p., lateral, in an upright position. Using the x-ray images, implant fractures, screw loosening spaces as well as screw dislocations were looked for. A loosening edge is defined as a fine hyperdense halo around the screw (bone reaction) with a hypodense zone between the screw and the hyperdense zone (loosening area).

The clinical results were compared with those from patients that had been treated, with Segmental Spine Correction System (SSCS® (pedicle screw – rod system with jointed head screw, but without coating) and a conventional posterolateral fusion.

RESULTS

From these 96 patients, 51 were female (53%) and 45 were male (47%). The age distribution was:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Patients</th>
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</thead>
<tbody>
<tr>
<td>31 - 40 years</td>
<td>3 patients</td>
</tr>
<tr>
<td>41 - 50 years</td>
<td>8 patients</td>
</tr>
<tr>
<td>51 - 60 years</td>
<td>30 patients</td>
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<tr>
<td>61 - 70 years</td>
<td>19 patients</td>
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<tr>
<td>71 - 80 years</td>
<td>31 patients</td>
</tr>
<tr>
<td>81 - 90 years</td>
<td>5 patients</td>
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Four additional patients could not be examined for their two-year check-up as they had died (three patients without any connection to the operation) or, in one case, had moved.

51 patients were stabilised in 1 segment, 35 patients in 2 segments, and 10 patients in 3 segments. In total, 494 screws, 192 longitudinal rods and 23 transverse stabilisers were implanted.

We compared the clinical results with a group of a total of 75 patients that had been treated with SSCS and a conventional posterolateral fusion.

In both groups, the indications were comparable: Symptomatic lumbar stenosis, painful olistheses, painful osteochondrosis, painful spondylarthrosis, recurring vertebral disc prolipsis, and discogenic pains.

The average age in the non-fusion group was 67.2 years, and in the fusion group 55.9 years. The reason for the increased age of the group without fusion is that, during the 1st year, we predominantly used the non-fusion technique for the treatment of older patients in order to keep the surgery trauma as low as possible. With increasing experience we then used the non-fusion technique also in the case of patients in the mid-range age of adult life.

In the non-fusion group, the average pain on the VAS (visual analogue pain scale) was 5.7 pre-operatively, and 2.9 post-operatively after one or two years, and in the fusion group the pains was 5.8 pre-operatively and 3.4
after one or two years. The Oswestry activity score in the non-fusion group was 25.4 points or 50.8% pre-operatively and 17.0 points or 34% post-operatively. In the fusion group, the Oswestry activity score was 23.7 points or 47.4% pre-operatively and 14.7 points or 29.4% post-operatively. The hospital stay in the non-fusion group was 7.4 days (6 – 18 days), and in the fusion group 16.9 days (9 – 36 days).

The surgery time (skin to skin) in the non-fusion group was 118.8 minutes (62 – 200 minutes), and in the fusion group 172.4 minutes (120 – 215 minutes). Perioperatively, a total of 0.60 units of eryxconcentrate were transfused (0 – 4 units), and, in the fusion group, 2.96 units of eryxconcentrate (0 – 6 eryxconcentrates) were transfused on average.

In the non-fusion group, revisions were carried out in the case of 4 patients (4.2% out of 96 patients) and, in the fusion group, revisions were carried out in the case of 6 patients (8.0% out of 75 patients). The revisions were caused by wound infections (1x in the case of the non-fusion group as well as 3x in the case of the fusion group), twice by symptomatic loosening of a screw in the non-fusion group, once by a screw breakoff in the non-fusion group and a total of three times due to a pseudoarthrosis in connection with an implant fracture or implant loosening in the fusion group.

In the non-fusion group, a total of 2 broken screws were found in the case of 2 patients, and in the case of 5 patients a total of 10 screws with loosening edges (2.4 % out of 494 implanted screws) were found. In total, 7 patients were affected; from these, 3 patients developed symptoms causing a revision to be carried out.

In the case of the revision, the loosened or broken screws were removed, the pedicle bore holes were filled with bone chips (similar to matchsticks) from the spinous process and then 7 mm cosmic revision screws were implanted. So far, there have been no new occurrences of renewed loosening or screw fractures in the case of these patients. In one case, a rod fracture occurred without any symptoms. There was no record of any screw dislocations or the fracture of a transverse stabiliser. All implant failures observed so far occurred within the first year.

Dlilisiiusss

Degenerative diseases of the lumbar vertebral column represent their own nosological entity. So far they have been treated primarily in accordance with the principles of deformities surgery and traumatology.

It was endeavoured to achieve a correction of existing deformities that is as complete as possible; and in order to ensure the result, rigid implants were used that are able to provide for three-dimensional correction if at all possible. The experience that the fusion of individual segments of the degenerative lumbar vertebral column may cause painful connection instabilities – and this applies obviously in particular to the rigid 360° fusions – increasingly poses a question mark over the use of such techniques for the treatment of degenerative diseases19-31.

The post-operative sagittal profile of the lumbar spine did not have any influence on the development of adjacent instabilities32.

In addition, there is the problem that in the case of older patients the quality of the bone frequently does not allow for any secure fixing of rigid implants, nor for any corrections. Some of the patients at an advanced age also show additional secondary diseases that cause the peri-operative complication rate in the case of more invasive operations on the vertebral column to increase.

Fusion as the gold standard for the treatment of chronic pain within the area of the degenerative lumbar spine must also be questioned, as a 100% spondylodesis is not the equivalent of a 100 % clinical success rate33,34.

The significance of patient selection is justifiably regarded as a decisive criteria for achieving a good clinical result35. For this reason it is not astonishing that there is a search for different alternative operative techniques that prevent any fusion36. However, what may possibly be astonishing is that it took so long to place a question mark over fusion as the gold standard. However, for some time already, there have been individual efforts to develop alternative solutions in relation to the fusion concept. The Graf band is possible the first pedicle screw supported non-fusion system for the treatment of painful degenerative instabilities on the lumbar spine. Biomechanically, it is to increase the use of dorsal tension chords and to reduce painful movements in the facet joints and in the disk. There are some reports about excellent clinical success37,38.

What remains disadvantageous are surely the missing rotational stability and the risk of an early failure of the cable. The dysenesis system represents a further development of the Graf system. The band is provided with a plastic sleeve, and the band is tensioned against this sleeve. This causes the stability to be increased, but also an increase in the load on the interface between vertebral bone and screw, which may cause a loosening to occur39. In relation to the rotational forces, the dysenesis system does not show any stability comparable to that of an intact vertebral column40. The clinical reports that have so far been published on the dysenesis system are mostly positive41. In combination with decompressions, these two systems are used somewhat more rarely as every partial removal of the facet increases the rotational instability42. Other non-fusion techniques, not based on pedicle screws, stabilise the motion segment by spreading the processus spinalis vertebrae and thereby also expand the spinal channel.

The indications are limited to light spinal narrowness and facet syndrome. Interspinous spreaders can be implanted minimum invasively. At this time, major clinical studies are not yet available. In contrast to the above-mentioned posterior non-fusion systems, cosmic is used for symptomatic spinalstenosis, in combination with decompressions, as well as in the case of purely discogenic or facet joint related pain.

The hinged screw provides for a sufficient degree of dynamisation and load sharing between the implant and the spine and prevents at the same time any rotation and translation instability. The rotation stability corresponds to that shown by an intact lumbar vertebral column43.
As non-fusion implants act like stability prosthesis and must last permanently without the protection of a fusion, the cosmic screw was additionally coated with Bonit in order to ensure a better anchoring in the vertebral bone. The clinical results found so far, when compared with conventional fusions, are equally good.

The perioperative trauma was much lower. The careful transmuscular (between muscleus multifidus and muscleus longissimus) access to the pedicles may further decrease the operation trauma.

Even when using cosmic, a careful selection of patients is the precondition for clinical success.

The radiological complex implant-related complications are in the lower range of those specified in the literature with regard to rigid implants in combination with a fusion. Here, between 2.5% and 15% screw fractures are specified.

Radiological loosening seams, as documented in the present study, are not really taken very much into account in the literature, unless they have noted screw dislocations. In fusion surgery as well as in non-fusion surgery, the meaning of implant-related complications cannot always be equated with a clinical failure. In those cases where a patient again develops pain after experiencing a temporary relief from complaints and where an implant-related complication can be radiologically detected, the revision is recommended in all cases. In principle, when using a non-fusion implant system, there is the option to carry out a conventional fusion in addition to the replacement of implants. The three patients revised in the present study due to symptomatic implant problems again received cosmic revision screws without fusion.

The results found so far with the cosmic system are very encouraging. However, additional long term observations are necessary.

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