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ORIGINAL ARTICLE

Late infections after dynamic stabilization of the lumbar spine with Dynesys

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Abstract
Introduction Dynamic stabilization of the spine was developed as an alternative to rigid fusion in chronic back pain to reduce the risk of adjacent segment degeneration. Dynamic neutralization system (Dynesys, Zimmer CH) is one of the most popular systems available, but some mid-term studies show revision rates as high as 30 %. Some late infectious complications in our patients prompted us to review them systematically. *Propionibacterium* recently has been shown to cause subtle infections of prosthetic material.
Materials and methods Here, we report on a consecutive series of 50 Dynesys implants. In a median follow-up of 51 months (range 0–91), we identified 12 infectious and 11 non-infectious complications necessitating reoperation or removal of the implant in 17 patients.
Results Material infections occurred after a median of 52 months (2–77) and were due to *Propionibacterium* alone ($n = 4$) or in combination ($n = 3$) in seven out of 11 patients. Clinical presentation combines new or increasing pain associated with signs of screw loosening on conventional X-rays; however, as many as 73.5 % of patients present some degree of screw loosening without being at all symptomatic of infection.
Conclusion The high rate of late infections with low-grade germs and the frequency of screw loosening signs made us suspect a lack of integration at the bone-screw interface. Surgeons should be suspicious if the patient presents a combination of new or increasing pain and signs of screw loosening, and aggressive revision is recommended in these cases.

Keywords Infection · *Propionibacterium* · Dynesys · Complications

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Introduction

In the past 20 years, dynamic stabilization of the spine has arisen as an alternative concept to rigid fusion in chronic back pain due to lumbar degenerative spinal disease or segmental hypermotility [2, 11, 12, 14, 17]. Dynamic neutralization system (Dynesys, Zimmer CH) was developed as an alternative to rigid fusion to prevent adjacent level disc degeneration, presumably due to adjacent segment hypermotility; to avoid donor site pain as well as other well-known complications of fusion surgery; and is one of the most popular systems available [1, 9, 15]. Many short- and mid-term follow-up studies have shown good results [18, 19]. However, some authors reported revision surgery rates as high as 30 % [3, 6, 8, 21]. No study has proven a restoration of physiologic weight balance or a protective effect on adjacent segments degeneration [13, 15, 19, 20].

Propionibacterium has been identified as a cause of prosthetic joint infections with subtle clinical presentation [22]. In a 10-year retrospective audit on instrumented spinal fusion, Collins et al. [4] showed that almost half of all the material infections were due to *Propionibacterium* and occurred as late as 5 years after surgery, exclusively after a posterior approach to the spine. However, the global incidence of infection remained low at 3.7 % (74/1,980 patients). *Propionibacterium* acnes is a slow-growing,

Table 1 Demographics

Number of operations	50	1 patient operated twice
Number of patients	49	
Sex ratio: women/men (%)	24 (48)/26 (52)	
Age at operation (years)	49 (29–72)	Median (range)
BMI	26 kg/m^2 (19.4–37.6)	Median (range)
Smoker status (0/1/2) (one missing data)	25/05/19	0 = never, 1 = <10/day, 2 = >10/day
Total clinical follow-up	57.5 months (6–91)	Median (range)
Last follow-up[a]	51 months (0–91)	Median (range)
Indication		
Instability	16 patients (32 %)	
Discopathy	34 patients (68 %)	
Operation time	135 min (70–295)	Median (range)
Previous lumbar surgery	16 patients (32 %)	
Number of segments		
1 segment	14 patients	
2 segments	16 patients	
3+ segments	20 patients	
Lowest segment		
S1	32 patients	Median 3 segments (1–6)
L5	13 patients	Median 1 segment (1–4)
L3–4	5 patients	Median 1 segment (1–2)
Total screws	342 (6 mm = 272, 6.4 mm = 68, 7.2 mm = 2)	
Deepness correction of screw	30 screws (8.77 %) in 21 patients (42 %)	
Radiological follow-up	24 months (1–77)	1 patient lost X-rays
Analyzed screws	328	1 patient lost to follow-up
Signs of loosening (halo)	103 screws/328 (31.4 %)	36 patients/49 (73.5 %)

[a] Until first complication or last consultation (completion of VAS-BP, VAS-LP pain, and ODI scores)

aerotolerant anaerobic gram-positive bacterium. It is part of the normal skin flora and is known to be linked to skin condition acne. We were confronted with a series of late infectious complications in our patients, which prompted us to review them systematically.

Materials and methods

We identified all patients who had a dynamic stabilization of the lumbar spine with the Dynesys system. Two senior spine surgeons in two hospitals did all operations and performed most of these together. Basic demographic data from the patients were collected. Their case notes and X-ray files were reviewed. Each patient completed a visual analogue scale for back pain (VAS-BP) and leg pain (VAS-LP), as well as the Oswestry disability index (ODI) at their last clinical follow-up or by direct phone contact. Radiologic follow-up and clinical follow-up times were noted separately. All patients presenting with either new or increasing lumbar pain with a halo on their X-ray were re-operated on to remove implants and to perform bacteriological analysis. All microbiology findings were reported. All tissue samples were bred for up to 14 days to allow slow-growing bacteria to be identified, especially the *Propionibacterium* species.

The implantation of the Dynesys system is systematically performed with the patient in prone position through a midline incision or a Wiltse approach. The patients receive general anaesthesia, and a prophylactic antibiotic therapy with Cefuroxime is started at the induction of anaesthesia and is continued for 48 h. Intraoperative protection of the implant was applied to reduce skin contamination. The technical aspects of implantation followed the surgical technique recommended by the manufacturer without inter-somatic cages. All screws used were of first generation (non coated) and at least 6 mm in diameter. Patients were allowed to walk on day one under physiotherapeutic coaching. Regular radiologic and clinical follow-ups are mandatory at 3, 6, 12, 18 and 24 months or on demand. All patients were contacted at the time of study. Only those with new or increasing pain were recruited for clinical and radiological exams.

Table 2 Patients and timing of complications

Compl. no	Pat. no	Indications for revision	Time to reop. (months)
1	2	Screw loosening and migration (L3 right, L5 bilateral)	41
2	6	Pseudarthrosis of operated segment (L4–L5)	13
3		Decompensation of adjacent segment (L3–L4)	58
4	7	Root compression of operated segment (L5 left)	2
5		Pseudarthrosis of operated segment (L4–L5)	26
6	8	Wound infection	1
7		Material infection (L2 right)	2
8	10	Material infection (Dynesys cord right)	52
9	14	Decompensation of operated segment (L5–S1 right)	0
10		Root compression of operated segment (L5 right)	1
11		Instability of operated segment (L4–S1)	15
12	16	Cortical perforation of operated segment (L4 right)	1
13	20	Material infection	52
14	21	Material infection (L3–S1 and Dynesys cord)	44
15	24	Material infection (Dynesys cord left)	60
16	28	Screw fracture (L2 left)	10
17		Material infection (L2–L5)	65
18	34	Material infection (L5 right)	57
19	35	Screw fracture and suspicion of infection (L4 right)	52
20	36	Material infection with migration of screw (S1 left)	47
21	37	Material infection (S1 left)	54
22	46	Material infection (L4–S1 and Dynesys cord)	77
23	48	Material infection (L2–S1 and Dynesys cord)	18

Compl complication, *no* number, *pat* patient, *reop* reoperation

Descriptive statistics was used to present basic demographic data. The student's *t* test and the Fisher's exact test were used as required.

Results

Between May 2002 and September 2008, 50 consecutive Dynesys implants were performed in 49 patients (one patient received a second operation with Dynesys 1 year after removal of implant due to early infection). All operated patients had low back pain resistant to at least 6 months of conservative treatment. Indication for surgery was lumbar low-grade instability in 16 patients and discopathy in 34 patients. Sixteen patients (32 %) had prior lumbar surgery, most of them micro-discectomy for disc herniation or fusion of neighbouring segments. The total number of implanted screws was 342 and the median screw diameter was 6 mm (range 6–7.2 mm). Thirty screws (8.77 %) in 21 patients (42 %) needed to be corrected with respect to deepness after fluoroscopic control during their initial operation. The total clinical follow-up was 57.5 months (range 6–91 months). There were seven patients (14 %), whom we could not reach to assess VAS-BP, VAS-LP and ODI scores. For those patients, we used the information obtained and X-rays performed at the last clinical control. Demographic data are summarized in Table 1.

Thirty-three patients had no complications at last follow-up; 23 complications necessitated operative revision among 17 patients; 12 complications (11 patients) were infectious and 11 (seven patients) non-infectious (see Tables 2 and 3). One patient had a mechanical complication after 10 months and a material infection after 65 months and, therefore, was counted in both groups but analyzed with the infection group. The infectious problems were diagnosed after a median period of 52 months, compared with a median of 13 months for the non-infectious complications. Four patients needed two follow-up operations, and one patient underwent three follow-up operations due to subsequent complications. One infectious complication necessitating removal of material occurred 2 months after the first operation and 1 month after wound debridement. The bacterium found was *Staphylococcus aureus*. In two cases material infection (*Staphylococcus epidermidis* at 54 months/*Propionibacterium* at 18 months) followed repetitive steroid infiltrations. The other infections occurred much later and had an insidious clinical presentation, mostly recurrent or increasing pain in combination with signs of screw loosening on follow-up radiological exams (see Fig. 1). Only one

Table 3 Indications for revision surgery

	Number of complications (number of patients)	Postoperative time (months in range)
23 complications in 17 patients[b]		
Infectious	12 (11)[b]	Median 52 (1–77)
Wound infection	1 patient (*Staphylococcus aureus*)	1 month
Material infection	11 patients	Median 52 (2–77)
Non-infectious	11 (7)[b]	Median 13 (0–58)
Screw loosening and migration	1	41
Pseudarthrosis	2	13 and 26
Decompensation of adjacent segment	1	58
Decompensation of operated segment	1	0
Root compression	2	1 and 2
Cortical perforation	1	1
Screw fracture	1	10
Screw fracture with suspicion of infection	1	52[a]
Instability	1	15

[a] Indication for revision surgery given, patient not re-operated

[b] Patient 28 had first a mechanical complication, followed by an infectious complication (see Table 2)

patient had classical signs of infection with fever, night sweats, high white blood cell counts and elevated C-reactive protein. The germs isolated during implant removal are summarized in Table 4.

Seven out of 11 patients (63.6 %) had single or combined infections with *Propionibacterium acnes*. One late infection (60 months) was probably also due to *Propionibacterium*: The gram coloration was positive, but the culture was unable to identify the bacterium, even after a 14-day breeding period. Other germs involved in late infections were *Staphylococcus epidermidis*, alone or in combination, as well as *Staphylococcus haemolyticus*, *Streptococcus oralis* and *Staphylococcus coagulase* negative in combination with *Propionibacterium*.

Mechanical complications are summarized in Table 3.

The re-operated group (all causes) was significantly younger ($M_{age} = 43$ vs. 50.5 years), and the duration of the initial operation skin to skin was significantly longer ($M = 163$ vs. 135 min., see Table 5). This difference in operation length also was seen in the comparison between infected and non-infected patients (168 vs. 138 min., see Table 6). The number of segments operated was equal ($M = 2.4$ levels) and did not explain this difference in duration. All other preoperative parameters were similar, especially smoker status, body mass index, indication for surgery and previous lumbar operation status. As expected, the re-operated and infected group performed worse in regards to VAS-BP, VAS-LP and ODI scores at the last clinical follow-up, but the difference was only significant for VAS-BP between re-operated and non-operated patients ($p = 0.035$).

Most of the patients had clinical improvement after removal of material and resolution of infection, which necessitated long antibiotic therapy and no need for new instrumentation.

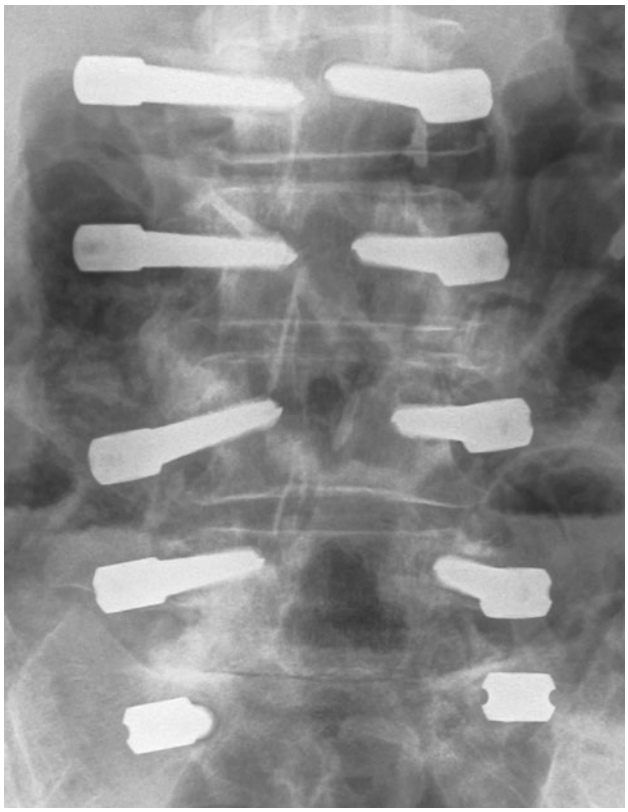

Fig. 1 Double halo L2 left + right, L5 left, S1 right, simple halo L3 left; posterior–anterior view; left on right side of picture

Median radiological follow-up after implantation of Dynesys with conventional X-rays was 24 months, with a broad range from 1 to 77 months. This is explained by the

Table 4 Microbiology results in material infections

	Number of patients	Postoperative time (months in range)
All material infections	11	Median 52 (2–77)
Staphylococcus aureus	1	2[a]
Staphylococcus epidermidis	2	47 and 54
Propionibacterium acnes	4	18, 52, 57 and 77
Propionibacterium acnes and mixed infection[b]	3	44, 52 and 65
Gram positive Cocci[c]	1	60

[a] This patient had a wound infection at 1 month postoperation

[b] Concomitant infections were *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Streptococcus oralis* and *Staphylococcus coagulase* negative

[c] Identification of bacteria was not possible

fact that some patients were re-operated on early, others were missing at follow-up and some patients had other radiologic modalities at follow-up. A total of 328 screws were analyzed, and 103 showed signs of loosening (simple or double halo sign, see Fig. 1). Thirty six out of 49 patients (73.5 %) had at least one loose screw on follow-up X-rays, and only 13 patients had all screws well integrated (see Fig. 2).

Discussion

This retrospective study achieved good data retrieval with only seven patients out of 50 (14 %) who were not available for clinical or telephonic assessment at last follow-up. The total observation time of nearly 5 years (Median = 57.5 months) also allows us to draw long-term conclusions. Our results at last follow-up ($M_{ODI} = 36.7$ %) were comparable to results after rigid fusion [7], and our VAS-BP of 4.8 and VAS-LP of 4.2 were similar to results obtained by Grob et al. after Dynesys implant [8]. Nevertheless, we could confirm our initial supposition of high incidence of late material infections in our patients.

Our revision rate of 34 % (17/50 patients), even if in the upper range, was comparable to that in the literature [3, 6, 8] and was explained by the long follow-up time in our study. What is new, to our knowledge, is the high incidence of infections (22 %) and especially their late presentation with a median of 52 months, peaking at 77 months. Excluding one early infection at 2 months that classically followed a wound infection with *Staphylococcus aureus*, and one mid-term infection with *Propionibacterium* at 18 months following repetitive infiltrations of the iliosacral joint, all other infections occurred after almost 4 years. Our clinical experience and case management is similar to that of Collins et al.. [4]. In most cases, a combination of recurrent or persistent lumbar pain with radiological signs of material loosening or a broken screw prompted the indication for revision surgery. Only one patient presented with classical symptoms of infection (night sweats, elevated white blood cells count, and C-reactive protein). The proportion of *Propionibacterium* infections was high (7/11 patients), but the spectrum of pathogens was still comparable to Collins et al.'s work. Additionally, in our experience, *Propionibacterium* is not only a contaminant, but also a germ with a clear pathogenicity for spinal implants, as confirmed by Gram-positive probe staining in this study. Interestingly, another study about deep surgical infections after spinal fusion [16] did not find *Propionibacterium* as a causative organism, confirming the difficulty of breeding this germ [22]. We found the same correlation between infectious risk and length of operation, but not with smoking habits or the number of operated levels [16]. And,

Table 5 Comparison between revised and non-revised cases

	Non-re-operated ($n = 33$)	Re-operated ($n = 17$)	p
Male/female	16/17	10/7	0.559[b]
Age (mean) years	50.5	43	*0.028*[a]
OP-time (mean) min.	135	163	*0.041*[a]
Indication (instability/discopathy)	11/22	5/12	1.000[b]
Previous lumbar operation (year/*n*)	11/22	5/12	0.723[b]
Screw corrections (year/*n*)	13/20	8/9	0.412[b]
Number of segments (mean)	2.42	2.41	0.974[a]
BMI (mean)	27.5	27	0.719[a]
Smoker status (year/*n*)	19/13[c]	5/12	0.989[b]
VAS-BP (mean)	4.18	6.2	*0.035*[a]
VAS-LP (mean)	3.89	4.73	0.398[a]
ODI score (mean)	31.75	46	0.068[a]
Halo on X-ray (year/*n*)	22/10[c]	14/3	0.249[b]
Mean follow-up (months)	47.5	34.2	0.063[a]

Significant p-values are in italics

[a] t test, [b] Fisher's exact test, [c] one missing data

Table 6 Comparison between infected and non-infected material cases

	Non-infected (n=39)	Infected (n=11)	p
Male/female	18/21	8/3	0.175[b]
Age (mean) years	49.6	42.1	0.055[a]
OP-time (mean) min.	138	168	*0.048*[a]
Indication (instability/ discopathy)	12/27	4/7	0.728[b]
Previous lumbar operation (year/n)	12/27	4/7	0.767[b]
Screw corrections (year/n)	16/23	5/6	0.529[b]
Number of segments (mean)	2.41	2.45	0.920[a]
BMI (mean)	27.7	26.1	0.391[a]
Smoker status (year/n)	20/18[c]	4/7	0.273[a]
VAS-BP (mean)	4.55	6	0.186[a]
VAS-LP (mean)	4.18	4.2	0.987[a]
ODI score (mean)	33.9	45.8	0.184[a]
Halo on X-ray (year/n)	27/11[c]	9/2	0.866[b]
Mean follow-up (months)	43	42.9	0.989[a]

Significant p-value is in italics

[a] t test, [b] Fisher's exact test, [c] one missing data

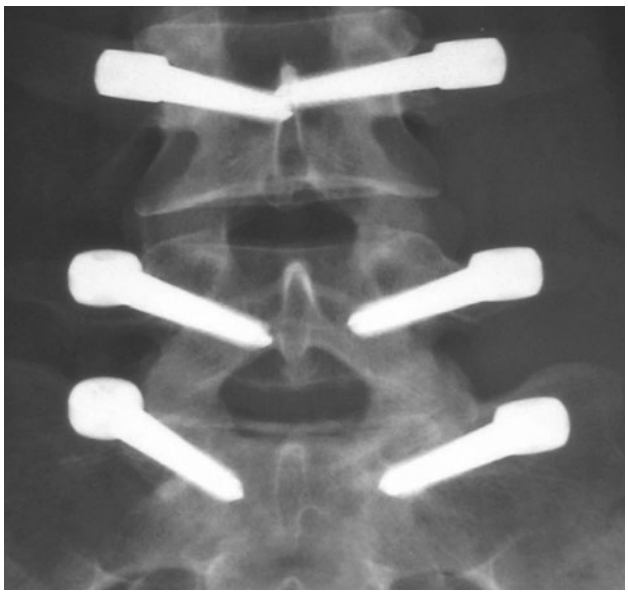

Fig. 2 No halo; posterior–anterior view; left on right side of picture

in opposition to our results, almost all infections occurred early with a median postoperative time of 13.5 days.

Among the preoperative parameters evaluated, we found no criteria that could help restrict the indication for Dynesys to a more favourable subgroup. Predictive factors are difficult to assess [10]. Bothmann et al. [3] described a tendency toward more screw loosening in younger patients. In our study, younger age was associated with a less favourable outcome without showing more screw loosening on conventional X-rays. Dakhil-Jerew et al. [5] suggested using the "double halo sign" to describe screw loosening. Even if they showed that this sign was associated with better inter-observer reliability, we think that, in the presence of new or increasing pain, every sign of screw loosening must be scrutinized and confirmed with a computed tomography or SPECT.

We do not have an explanation for the high rate of long-term infections observed in our patients. In view of the frequency of signs of screw loosening observed (73.5 %, 36/49 patients), we hypothesize that there is a biomechanical lack of integration at the bone-screw interface probably due to the screw design. This could eventually lead to a chronic inflammation with a "dead space" prone to opportunistic skin-flora super infection and should be cleared in further animal or experimental studies. Meanwhile, new screws coated with hydroxyapatite have been developed by the same manufacturer to achieve better tissue integration, and they may reduce the risk of screw loosening. This needs further study to confirm.

Finally, systematic implant removal after a 3-year period remains an open question in our group.

Conclusion

In this small series of patients, we detected an abnormal level of late infections. We did not find any correlation with the screw diameter or operated levels. We found a slightly longer operation time in the infected group, but we do not think that a perioperative contamination explained those late infections.

Biomechanical design of the screw could be the main factor of poor screw-bone integration.

We strongly advise performing long-term follow-up on patients implanted with Dynesys and removing implants in patients with new or increasing pain and radiological signs of screw loosening.

Conflict of interest None.

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