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Follow-up note / Original Article

Knee arthrodesis using a custom modular intramedullary nail in failed, infected knee arthroplasties: A concise followup note of 31 cases at a median of 13 years postarthrodesis

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Abstract

Introduction:

Knee arthrodesis utilizes an arthrodesis nail as a salvage technique for infected total knee arthroplasty (TKA), especially when the extensor mechanism is damaged, or the skin is compromised. This implant helps to minimize or prevent leg length discrepancy, while allowing immediate weight-bearing without requiring bone fusion. However, there is a risk of infection. Surgical revisions were required in 19% of patients at 50 months' follow-up in our team's initial 31patient case series. Since there is little long-term outcome data, we reviewed this same group of patients after a mean of 13 years to determine: 1) the implant's long-term survival, 2) the functional outcomes, 3) the microbiological changes in revision cases.

Hypothesis:

The long-term survival of knee arthrodesis using an arthrodesis nail for failed infected TKA is acceptable.

Material and Methods:

Thirty-one patients operated on between January 2005 and December 2008 were retrospectively included in the initial study. The functional outcomes consisted of pain on a visual analog scale (VAS), neuropathic pain (DN4) and the Oxford Knee Score. All surgical revisions were documented with repeat microbiology samples.

Results:

The median follow-up time was 13.1 years [11.5-13.5]. No mechanical failure (implant failure or aseptic loosening) was observed. Eight patients were re-operated on due to new infections. The nail had to be removed in five of these patients. None of the patients required an amputation. Among the eight patients who were re-operated on, only two (25%) had been re-operated on since the initial study and underwent a two-stage arthrodesis revision.

At 10 years, the cumulative incidence of surgical revision at the knee was 26% [95% CI: 12%-43%] and 16% [95% CI: 5.7%-31%] for an implant change. Six (75%) of the reoperated patients had their revision within the first 72 months of the initial TKA, while 4 (50%) had it within the first 26 months. Among the 15 patients who were still alive, the median Oxford Knee Score was 17/48 [12-28]. At the final assessment, the median pain level was 0 [0–5], although 4 of the 10 analyzable patients (of the

15 living patients, 3 had a cognitive impairment and 2 refused to participate) had neuropathic pain and pain on VAS of 3/10. The microbiologic findings were the same during the surgical revision in five of the eight reoperated patients (62%); however, one patient who had a Staphylococcus aureus infection had acquired a resistance to methicillin. In one patient, only one of the two bacteria identified initially was still present (methicillin-susceptible Coagulase-negative staphylococci [CNS]) and while in two patients, the infectious agent changed completely (shift from Gram-negative bacilli to methicillin-susceptible CNS, and the opposite for the other patient).

Discussion:

Knee arthrodesis with a custom modular intramedullary nail is a viable limb salvage option in failed infected TKA cases with long-term survival, and it is comparable to other arthrodesis techniques. In most cases, recurrence of the infection occurred in the short term (<72 months). Later recurrences of the infection (> 72 months) were rarer and were found in only two of our patients (6%). There were no mechanical failures.

Level of evidence: IV; Retrospective cohort study Key words: Knee, Arthrodesis, Infection, Total Knee Arthroplasty

1 Introduction

Knee arthrodesis has been proposed as a salvage technique in infected total knee arthroplasty (TKA) to avoid above-knee amputation, especially when the extensor mechanism is ruptured [1-3]. Several studies have shown it to be superior to repeated TKA revisions when the infection recurs [1-4]. While many surgical techniques exist, nail arthrodesis is the only one that leads to satisfactory clinical outcomes without bone fusion, while allowing immediate weight bearing and minimizing leg length discrepancy (LLD) (**Figure 1**) [2,3]. Nevertheless, the presence of a foreign body in an infected site theoretically increases the risk of infection recurrence, although this point has not been

investigated over the long term (> 10 years). Using the same cohort of patients evaluated by Putman et al. [3] in 2013, who had found 77% survival at 50 months' follow-up, we re-evaluated these patients after at least 11.5 years of follow-up.

To our knowledge, no other study has repeatedly evaluated the same set of patients who had received an intramedullary arthrodesis nail for failed infected TKA. The nail's volume and large stresses are causes for concern about recurrence of the infection or failure of the device [4]. This led us to do a concise follow-up study at 10 years on the cohort published in 2013. The aims were to 1) determine the long-term survival, 2) specify the stability of the functional outcomes, 3) study how the microbiology changes in revision cases.

2 Material and Methods

2.1 Patients

The patients for this retrospective study were the same as in the study by Putman et al. [3]. All patients who had undergone knee arthrodesis due to a failed, infected TKA at the French Referral Center for Treatment of Bone and Joint Infections (CRIOAC) in Lille-Tourcoing between January 2005 and December 2008 were included retrospectively. Thirty-nine patients underwent arthrodesis: 8 patients who treated with an external fixator were excluded while the other 31 were treated with a cementless modular intramedullary nail (Link Endomodel, Boves, France) (Figure 2). There were 19 women (61%) and 12 men (39%) who had a mean age of 67 ± 12 years (48–80 years) at the time of arthrodesis. During the initial study in 2012, three patients had undergone debridement and lavage before suppressive antibiotics, three patients had their implants changed (thus 6/31 failed due to infection or 19%) while three patients had died.

2.2 Methods

Twenty-five patients (81%) had undergone two-stage revision while 6 patients (19%) had undergone single-stage revision following a decision of the multidisciplinary care team. The antibiotic treatment

was derived from the study of Zimmerli et al. [5] and followed a protocol reviewed annually with empirical antibiotic therapy that is adapted secondarily to the infectious agent identified after culturing the intraoperative samples.

2.3 Assessment methods

The patients were reviewed regularly in person with a physical examination, radiographs and functional scores. The Oxford knee score [6,7] was determined at every follow-up visit. Starting in June 2018, pain on visual analog scale (VAS) and the DN4 score (neuropathic pain) [8] were added to the follow-up assessments. In the deceased patients, the cause of death was determined to rule out a link with surgery.

2.4 Statistical analysis

Qualitative variables were expressed as counts and percentages. Quantitative variables were expressed as median and interquartile intervals. The cumulative incidence of new surgery was estimated using a competitive risk model by considering death as a concurrent event. The same method was used to estimate the cumulative incidence of implant change. The overall survival was estimated using the Kaplan-Meier method. The statistical analysis was performed with SAS software (version 9.4, Cary, NC, USA).

3 <u>Results</u>

The median follow-up was 158 months [138–163], or 13.1 years [11.5–13.5]. There were no mechanical failures (implant breakage or aseptic loosening). Eight patients (26%) had to undergo revision surgery, and all had infections. Five patients (16%) had their implants changed while three patients (10%) underwent debridement and lavage before suppressive antibiotics. Among the five revisions:

- One female patient suffered a fracture then septic non-union between the arthrodesis
 prosthesis and short intramedullary locked nail; she then received a total femur prosthesis
 with knee arthrodesis component.
- One male patient had failed lavage; he underwent a revision to remove the nail and arthrodesis with external fixator. Bone union was achieved without recurrence.
- Three patients underwent two-stage nail change for recurrence of the infection (one had radiographic signs of loosening) and all were without recurrence.

Among the three patients who underwent debridement with implant retention, one patient received suppressive antibiotic treatment and had a well-tolerated chronic fistula. The two other patients had no recurrence.

Among these surgical revisions, only two occurred since the 2012 study; both were two-stage revisions, including the one with radiographic septic loosening. All the other surgical revisions had been done before 2012 (**Figure 3**). The cumulative incidence of implant change and surgical revision at 10 years were 16% [95% CI: 5.7%–31%] (**Figure 4**) and 26% [IC 95% 12%-43%] (**Figure 5**) respectively. Sixteen patients had died (three at the 2012 review and 13 since then), although none of these patients had died from complications related to the arthrodesis or recurrence of the infection. The 10-year survival rate was $52\% \pm 0.1\%$ (**Figure 6**). The life expectancy with an arthrodesis implant was 156 months (13 years) after the surgery.

During the surgical revisions, the same bacteria was found in five of the eight patients (62%) who required revision. However, one patient was infected by S. aureus that had become methicillin-resistance during the revision (Table 1). The changes in the infectious agent in the three other patients were:

• One patient still had a methicillin-susceptible Coagulase-negative staphylococci infection although the Gram-negative bacteria (*E. Cloacae*) isolated initially was not found during the recurrence.

- Another patient who had a methicillin-susceptible CoNS and Enterococcus infection became infected with a Gram-negative bacterium (*Citrobacter koserii*)
- The final patient was initially infected by a Gram-negative bacterium (Fusobacteriume) and had a recurrence with methicillin-susceptible CoNS (Table 1).

The Oxford knee score in the 15 patients who were still alive was 17/48 [12–28], which was comparable to the 2013 result of 18/48 [9–31] [3]. The pain on VAS and DN4 data could be analyzed in 10 patients (16 patients had died, 3 no longer had the intellectual capacity to fill out the DN4 questionnaire and 2 refused). The DN4 score was positive in 4 of the 10 patients analyzed (median 0.25 [0–6]), thus highlighting the importance of neuropathic pain. The patients who had a positive DN4 also had pain on VAS above 3, while the other patients all had pain levels of 3 or less. For the entire population at the final assessment, the median pain level on VAS was 0 [0–5].

4 Discussion

The press-fit modular arthrodesis nail has an acceptable long-term survival without implant revision, with most surgical revisions done within 72 months. These findings are comparable to other studies [2,8–14] on arthrodesis nails in which 10-50% of patients had to undergo repeat surgery but with shorter follow-ups (16–67 months). This is the first study with 10-year survival data for knee arthrodesis using an arthrodesis nail for failed infected TKA.

However, the other currently used arthrodesis techniques have lower infection recurrence rates. Several studies of short [15,16] and long intramedullary nails [17,18] report a recurrence rate of 0% to 8%. External fixators [19–22] also have good results with remission of the infection between 0% and 6%. However, in cases of large bone defects, an arthrodesis nail is the only way to minimize LLD (Table 2).

Arthrodesis makes it possible to postpone amputation, which has poor outcomes with only 40% of patients fitted with a prosthesis and 31% rate of local infection recurrence [23]. The life expectancy

with an arthrodesis nail has never been specified in published studies. Nevertheless, the mortality rate in other arthrodesis studies, all techniques combined, ranges from 4% to 22% [9,17,18]. The Oxford Knee Score in our study was lower than in other published studies: De Vil et al. [24] and Neuerburg et al. [10] reported scores of 25/48 and 20/48 versus only 17/48 in our study. These functional scores show poor functional outcomes in all cases, which can be explained by the loss of mobility after arthrodesis modifying the quality of life in patients who initially underwent TKA. The microbiology findings were identical for the most part during the revision surgery and pointed to a recurrence instead of a new infection (superinfection).

Our extensive follow-up allowed us to add new information, in particular about neuropathic pain, which is definitely present in some patients and may partly explain the poor functional outcomes. No other study on arthrodesis nails or arthrodesis implants provides information about neuropathic pain.

Our study has certain limitations.

1) The population was relatively small, with only 15 patients still alive at 13 years' follow-up; however, no patients were lost to follow-up and this is the first study with more than 10 years' follow-up.

2) The mortality rate was high but not unexpected given the mean age of the patients (67 years) at the time of arthrodesis, and their serious comorbidities (13/31 were diabetic) with 7 patients having an ASA score of 3 [3].

3) Except for the Oxford Knee Score, the other outcomes were added later and were analyzed in only one-third of our patients. Nevertheless, in the patients analyzed, the Oxford Knee Score changed little over time. Conversely, this study was the first one to reveal persistent long-term neuropathic pain, even after knee fusion.

4) While no patients were lost to follow-up, some patients had major cognitive deficits that prevented them from filling out patient-reported outcomes. We could not do a refined analysis of

the functional change in our patients; however, their overall status was captured by the Oxford Knee Score, which had a complete data set.

5 <u>Conclusion</u>

Using an arthrodesis nail as salvage technique for failed and infected TKA is a viable solution given its acceptable survival at 10+ years, its reasonable functional outcomes and advantages, particularly the absence of major LLD and ability to bear weight immediately postoperatively. It can be proposed to patients with recurrent TKA infections, especially when the extensor mechanism is ruptured or there is a high risk of skin damage.

Conflict of interest: Henri Migaud is the editor-in-chief for Orthopaedics & Traumatology: Surgery & Research; none of the other authors have a conflict of interest related to this work. Outside this work, Henri Migaud is a research and educational consultant for Zimmer-Biomet, Corin, MSD and SERF. Outside this study, Sophie Putman is a research and educational consultant for Corin. Eric Senneville is a paid speaker for Zimmer-Biomet and is a consultant for MSD, Pfizer, Correvio, Bayer, Sanofi-Aventis and Cepheid. The other authors have no conflict of interest to declare outside this study.

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Contributions:

PAF collected data and wrote the article

SP helped design the study, provided the patients with surgical treatment, analyzed data and corrected the article

ES helped design the study and provided the patients with medical treatment

EB provided the patients with surgical treatment

HM helped design the study, provided the patients with surgical treatment, analyzed data and

corrected the article

HB did the statistical analysis and corrected the article

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Figure legends

Figure 1: Bone loss leading to leg length discrepancy when the joint is fused instead of using an arthrodesis implant. A: Total knee arthroplasty, B: Bone loss after removal of the TKA, C: Fusion requires bone-to-bone contact, thus shortening of the limb by an amount at least equal to the bone loss, D: Since fusion is not required with an arthrodesis implant, the amount of shortening is set by the surgeon.

Figure 2: Example of arthrodesis nail at 13.5 years' follow-up

Figure 3: Flow chart showing the revisions that were done since the original study by Putman et al. in

2013 [3]. DAIR = debridement, antibiotics and implant retention, DN4 = neuropathic pain

questionnaire, VAS = visual analog scale

Figure 4: Cumulative incidence of implant removal. Most of the removals occurred before 50 months Figure 5: Cumulative incidence of new surgery consisting of lavage and implant revision Figure 6: Estimated survival, all causes included Table 1: Microbiology results during the initial arthrodesis implantation and the revision surgery.Patients operated since the original study are in bold. a: different bacterium, b: recurrence with

same bacterium, c: acquired resistance

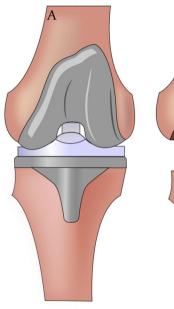
| Patient | Initial microbiology findings | Revision microbiology findings |
|-----------------------|--|--------------------------------|
| 1 ª | CoNS-MS and GNB (Enterobacter cloacae) | CoNS-MS |
| 2 | SA-MR | |
| 3 | SA-MS and CoNS-MS | |
| 4 ^b | SA-MS | SA-MS |
| 5 | SA-MS | |
| 6 | GNB (E. coli) and Enterococcus | |
| 7 | SA-MS | |
| 8 ^b | Enterococcus | Enterococcus and SA-MS |
| 9 | SA-MS | |
| 10 ^b | CoNS-MR | CoNS-MR |
| 11 | GNB (P. aeruginosa) | |
| 12 | CoNS-MS | |
| 13 | SA-MS and Streptococcus | |
| 14 | CoNS-MS | |
| 15 | 2 CoNS-MS | |
| 16 | Streptococcus | |
| 17 ^a | CoNS-MS and Enterococcus | GNB (Citrobacter koserii) |
| 18 | CoNS-MS | |
| 19 | CoNS-MS | |
| 20 | Streptococcus | |
| 21 ª | GNB (Fusobacterium) | CoNS-MS |
| 22 | GNB (P. aeruginosa) | |
| 23 | 2 CoNS-MS | |
| 24 ^c | SA-MS | SA-MR |
| 25 | SA-MS | |
| 26 | CoNS-MS | |
| 27 | SA-MS | |
| 28 | SA-MS | |
| 29 ^b | SA-MS | SA-MS |
| 30 | GNB (E. coli) | |
| 31 | Streptococcus | |

MR: methicillin-resistant; MS: methicillin-susceptible, GNB: Gram-negative bacilli, SA: S. aureus; CoNS:

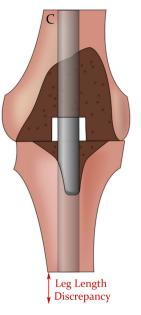
Coagulase-negative Staphylococci

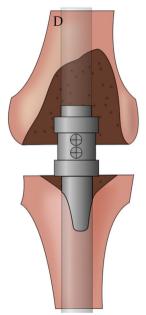
Table 2 Main published studies on the outcomes of arthrodesis on infected total knee arthroplasty (LLD: leg length difference)

| AUTHOR | YEAR | PATIENTS | TYPE OF ARTHRODESIS | FOLLOW-UP (MONTHS) | NEW SURGERY | INFECTION RECURRENCE | FUSION RATE | LLD (CM) |
|------------------------------------|------|----------|---------------------------------|-----------------------|----------------|-------------------------|-------------|----------|
| GALLUSER et al. [15] | 2015 | 15 | Short intramedullary nail | 33 | 33.3% | 0.0% | 75.0% | |
| LEE et al. [16] | 2011 | 8 | Short intramedullary nail | 52 | 0.0% | 0.0% | 100.0% | 1.1 |
| BARGIOTAS et al. [17] | 2007 | 12 | Long intramedullary nail | 49 | 16.7% | 8.3% | 83.3% | 5.5 |
| LEROUX et al. [18] | 2013 | 17 | Long intramedullary nail | 16 | 11.8% | 5.9% | 94.1% | 2.8 |
| IACONO et al. [19] | 2013 | 12 | Ilizarov external fixator | 93 | 20.0% | 0.0% | 90.0% | 4.5 |
| OOSTENBROEK & VAN ROERMUND [20] | 2001 | 15 | llizarov external fixator | 52 | | | 93.0% | |
| BALCI et al. [21] | 2016 | 17 | Uniplanar external fixator | 52 | 29.4% | 5.9% | 94.1% | 2.9 |
| PARRATTE et al. [22] | 2007 | 18 | Dual uniplanar external fixator | 85 | | 0% | 88.9% | |
| HAWI et al. [11] | 2015 | 27 | Arthrodesis implant | 105 | 14.8% | 14.8% | | |
| IACONO et al. [8] | 2012 | 22 | Arthrodesis implant | 34 | 14.3% | 14.3% | | 0.8 |
| RAO et al. [14] | 2009 | 7 | Arthrodesis implant | 39.6 | 28.6% | 14.3% | | |
| RÖHNER et al. [9] | 2015 | 26 | Arthrodesis implant | | 50.0% | 50.0% | | |
| OUR STUDY | 2020 | 31 | Arthrodesis implant | 149 | 26.1% | 26.1% | | 1.0 |



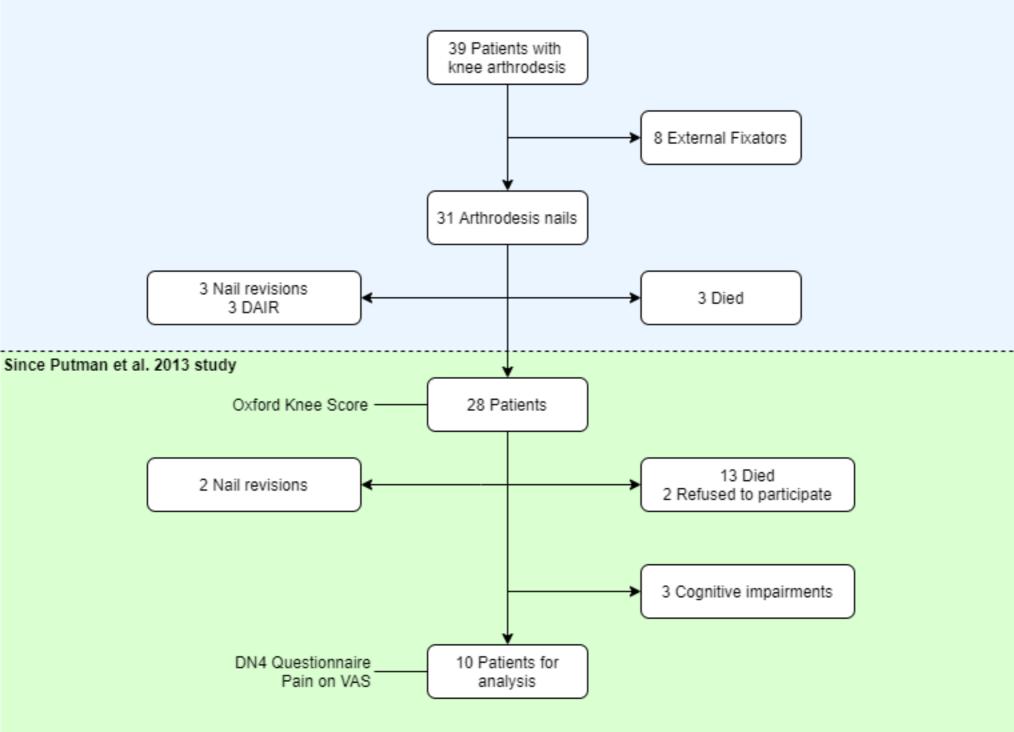




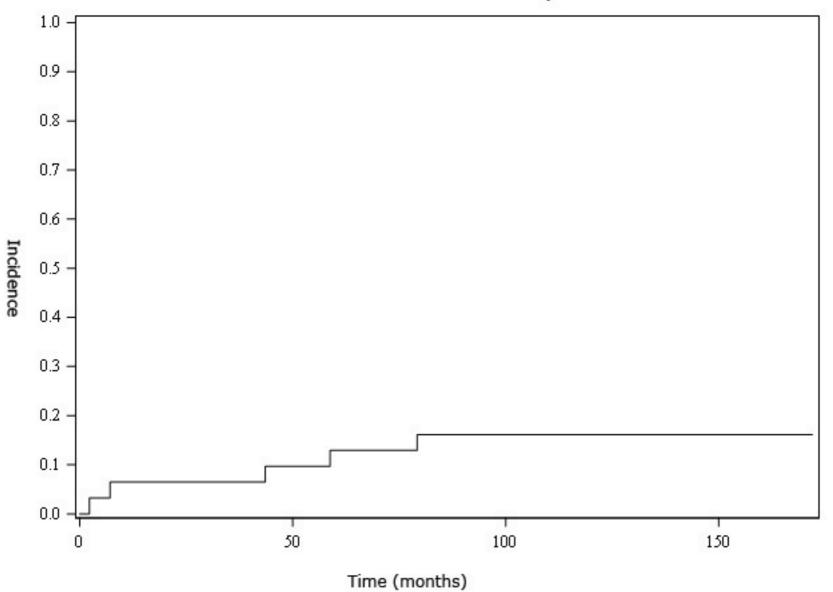




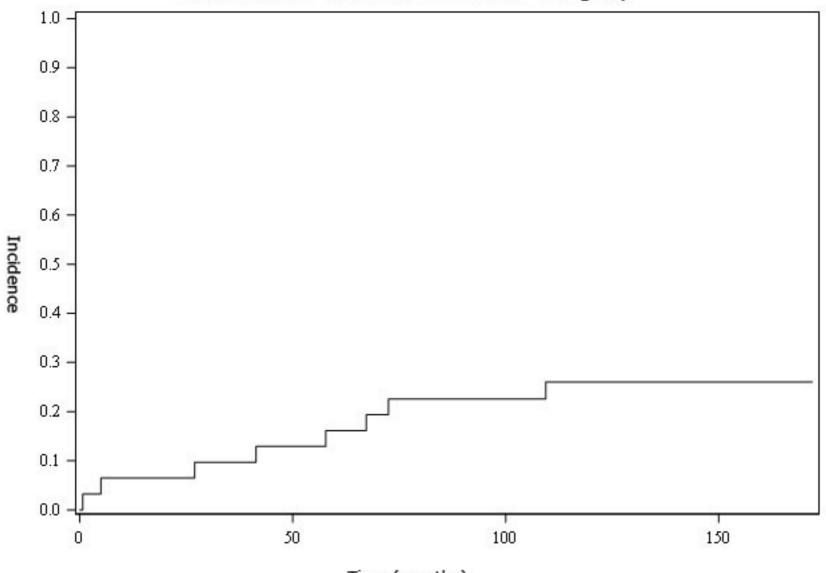
Putman et al. 2013 study



Cumulative incidence of Implant Removal



Cumulative incidence of New Surgery



Time (months)

Kaplan Meier survival estimate

