Cementless modular intramedullary nail without bone-on-bone fusion as a salvage procedure in chronically infected total knee prosthesis: long-term results

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Abstract

Purpose Our purpose was to evaluate long-term results of two-stage cementless intramedullary nailing without achieving bone-to-bone fusion for treating chronically infected total knee arthroplasty (TKA).

Methods Thirty-eight patients treated according to the same protocol were retrospectively evaluated for clinical, functional, laboratory and radiological outcomes.

Results Spacer exchange was necessary for infection persistence in one case. At a minimum two year follow-up, 34 patients (89.5 %) showed no infection recurrence; among these 34 patients, 29 (85.3 %) reported no or moderate pain [visual analogue scale (VAS) ≤ 3]; mild to moderate handicap (Lequesne Algofunctional Index < 7.5) was observed in 18 patients (52.9 %). No patient underwent revision for aseptic loosening, and no nail breakage was observed.

Conclusions Two-stage cementless intramedullary nailing without achieving bone-to-bone fusion is a viable option for treating chronically infected TKA in selected, complex cases.

Keywords Infection · Knee · Nail · Two-stage · Prosthesis

Introduction

Postsurgical infections represent a common healthcare problem, with *Staphylococci* being the leading microorganism involved [1, 2]. In the orthopaedic field, the issue posed by bacterial infection is considerable, especially because multi-drug-resistant microorganisms are among the most frequently reported agents associated with orthopaedic implant infection [3]. Whereas infection after primary joint replacement in normal hosts is relatively rare, occurring in < 2 % of patients, septic complications may be much more frequent in immunocompromised hosts or after revision surgery [4]. Moreover, despite the relatively low incidence of postsurgical septic complications, their overall socioeconomic burden will increase due to various factors [5]. Different treatment strategies can be adopted to counteract orthopaedic infections, depending on overall patient conditions (immune system, joint status and its functionality...) and according to involved pathogens and infection severity [6]. In the vast majority of infected total knee arthroplasty (TKA), one- or two-stage exchange is the preferred option to eradicate infection, with success rate ranging from 80 % to 100 % in different studies [7].

In selected cases, however, knee arthrodesis has been proposed as a salvage procedure. This procedure was first performed for poliomyelitis, and common indications throughout the 1900s included malignant knee tumor, benign, local, destructive tumor, aseptic loosening and posttrauma [8]. Nelson and Evarts were probably the first to report knee arthrodesis as a treatment for failed TKA [9]. Knee arthrodesis has thereafter been proposed for septic knee prosthesis in the presence of one or more of the following conditions: highly virulent or multi-drug-resistant microorganisms, extensor apparatus deficit, severe bone loss or soft-tissue defect, multiple previous revision surgeries and patient's refusal to further prosthesis reimplantation or amputation [10–18].

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Different techniques for knee arthrodesis have been reported, including plate and screw osteosynthesis, external fixation and intramedullary nailing, the latter two being the most often preferred in the presence of bone infection [10, 12, 13, 15, 18–21]. Whereas the proposed techniques do achieve bone fusion and infection control in the majority of cases, residual limb-length discrepancy and possible nonunion are the primary limits of knee arthrodesis following septic TKA. To overcome these problems, intramedullary nailing without bone fusion has been recently proposed in limited series of patients [17, 22]. Advantages of this option include no need for bone fusion and hence no risk of nonunion, early recovery and reduced limb-length inequality.

Aim of this retrospective case series study was to evaluate the long-term clinical, radiological and functional results in a continuous series of patients affected by chronic periprosthetic TKA infection, treated according to a same protocol of two-stage cementless modular intramedullary nailing without knee fusion.

Materials and methods

We retrospectively reviewed two cohorts of patients managed at the Istituto Ortopedico IRCCS Galeazzi and at the Istituto Ortopedico G. Pini in Milano, Italy, for chronic TKA infection between 2000 and 2011. The study was performed in accordance with the Declaration of Helsinki of 1975 as revised in 2000 and was approved by the respective local Ethical Committees. Inclusion criteria were the following:

- Patients diagnosed with chronic TKA infection with at least a six months duration according to Spanghel criteria [23]
- Patients treated according to a same protocol of a two-stage implant, with cementless modular nail acting as a fixed knee prosthesis, without bone-to-bone fusion
- Minimum follow-up 24 months.

In all, 38 patients (18 men, 20 women) were available for review; three other patients, lost to follow-up within one year from surgery in one case or with insufficient data in the remaining two cases, were excluded.

Surgical technique

In all cases a two-stage procedure was undertaken. In the first stage, removal of the septic TKA and antibiotic-loaded cement, accurate surgical debridement and insertion of an antibiotic-impregnated cement spacer, were performed. For spacer preparation and fixation, antibiotic-loaded cement, either CEMEX Genta (Tecres® Somacampagna, Italy) or Simplex® Erythromycin and Colistin (Stryker Inc., Kalamazoo, MI, USA) were chosen on the basis of the isolated

microorganism and intraoperatively mixed with 3 g of Vancomycin per cement pack. Multiple specimens of soft tissues and periprosthetic bone samples from the femur, tibia and joint were sent for microbiological examination. Postoperatively, antibiotics were given intravenously for two weeks and then orally for two to four weeks, empirically chosen or according to culture results when bacteria were identified. Antibiotics were then discontinued for at least four weeks prior to nailing; second-stage procedure was performed in the absence of clinical signs of infection recurrence and return of C-reactive protein (CRP) to values ≤ 1.5 mg/L.

The second stage consisted of removing the spacer, further surgical debridement and tissue sampling for microbiological analysis. An intramedullary modular nail (Endo-Model® Knee Fusion Nail SK Modular System®, Waldemar-Link, Hamburg, Germany) was implanted without cement in all cases. To this aim, femur and the tibia were reamed until the cortical bone was reached and the femoral and tibial stems, provided with a sanded titanium surface, were then press-fit inserted into the diaphyses. The two components were then linked to each other by reciprocal interlocking of their base plates and fixed with two anteroposterior screws. Once assembled, nail valgus angle in the frontal plane features 5° and 5° flexion in the sagittal plane. No attempt was made to match femoral and tibial metaphyses to obtain joint fusion, and no bone grafting was undertaken. Instead, antibiotic-loaded bone cement was applied in the joint space to achieve local antibiotic delivery and to further fill the joint space, as needed (Fig. 1). No tourniquet was used in any patient except during the cementing phase in the joint space. No cast or brace were used postoperatively. All patients were encouraged to gradually resume full weight bearing on the operated limb within three months of surgery. After surgery, systemic antibiotic therapy was administered according to the same protocol followed during the first stage.

Outcome evaluation

The following clinical criteria were assessed:

- Scar condition, signs of local and/or systemic infection (intra-articular effusion, local heat and/or erythema, sinus tract, fever)
- Detection and measurement of leg-length discrepancy and need for cane or crutches
- Visual analogue scale (VAS) using the 10-cm-graduated scale for pain self-assessment
- Lequesne Algofunctional score [24] to assess handicap severity felt by patients in their daily life; low scores correspond to good results

Radiographs were assessed for signs of osteolysis around the implant, and erythrocyte sedimentation rate (ESR) and

Fig. 1 **a** Pre-operative clinical finding. Soft tissue defect and full-thickness lesion of the patellar tendon. **b** Postoperative X-ray 5 years after second-stage reconstruction. Modular cementless intramedullary nail is in

place. Only the joint space is filled with antibiotic-loaded cement. **c** Clinical aspect after 5 years from nailing

C-reactive protein (CRP) level were measured. Full recovery was defined by the presence of all of the followings: no local signs of inflammation or draining sinus, normal ESR and/or CRP, no need for further antibiotic therapy and no need for revision surgery at any time from index operation [25].

Results

Preoperative data

Mean age at the time of index surgery was 65 ± 14 (range, 46–82) years. Mean number of previous surgeries was 6.8 (two to 18). All patients were followed up for a mean of 62 ± 34 (24–105) months. At the time of surgery, all patients had one or more of the following conditions: periprosthetic infection due to multi-drug-resistant and highly virulent microorganism(s), severe bone loss, soft tissue defect, severe knee stiffness, deficit of the extensor knee apparatus, immunocompromised host, previous several failed surgeries and patient refusal of other surgical options. Microbiological findings showed negative cultures in nine patients (23.7 %); 13 (34.2 %) showed mixed flora. *Staphylococcus aureus* was isolated in 19 cases (50.0 %), including ten with methicillin-resistant strains; coagulase-negative staphylococci were identified in 12 patients (31.6 %) (five methicillin-resistant). Other isolates were *Streptococcus* spp. in five patients (13.1 %), *Pseudomonas aeruginosa* in three (7.8 %), *Enterobacter* spp. in three (7.8 %), *Escherichia coli* in three (7.8 %), *Enterococcus faecalis* in three (7.8 %) and other in four (10.5 %).

According to McPherson's classification [26], 12 patients (31.6 %) were considered type A hosts, 19 (50 %) type B and seven (18.4 %) type C. Diabetes, smoking, renal insufficiency, peripheral vasculopathy and rheumatological disorders were the most commonly observed comorbidities.

Postoperative results

Spacer exchange was necessary for infection persistence in one case; in this patient, infection persistence was attributed to the concomitant infection of an internal osteosynthesis in the proximal third of the femur that was not removed during first-stage procedure. One more patient experienced an intra-operative femoral shaft fracture during nail insertion, which was treated by osteosynthesis with plate and screws. This patient developed an infection recurrence three years later and finally underwent above-knee amputation after further failed plastic surgery and nail exchange. Other complications at the time of surgery were two deep vein thrombosis, one pneumonia and four delayed wound healing.

Overall, at a minimum of two years follow-up, four of 38 patients (10.5 %) developed infection recurrence; one was treated with surgical debridement, exchange of the modular part of the nail and suppressive antibiotic therapy; one underwent one-stage nail exchange; two were treated with above-knee amputation, one three years from index operation, as reported above, and another one who refused further surgery 18 months after nail implant. Among the remaining 34 patients, two (5.9 %) reported pain in the operated leg at rest (VAS 1 and 2, respectively), whereas mean VAS for pain during walking was 1.1 (range 0–5): 20 patients (58.8 %) had no or very mild pain (VAS=0–1), nine (26.5 %) moderate pain (VAS 2–3) and five (14.7 %) had more severe pain (VAS 3–5).

The mean Lequesne Algofunctional index was 10.3 (range 2.5–19.5); mild to moderate handicap (score <7.5) was reported by 18 patients (52.9 %), and the remaining 16 (47 %) reported severe or very severe handicap (score >7.5). All patients required a cane or crutches for long walking distance (> 500 m; short-distance walking was possible without aids in 27/34 patients (79.4 %). Occasional ipsilateral hip pain was reported by five patients (14.7 %), four (11.7 %) reported contralateral knee pain with radiographic evidence of osteoarthritis and two reported painful knee prosthesis. All patients

found it difficult to climb stairs and sit in cars. The average limb-length discrepancy was 1.3 cm (range 0–4 cm).

At the latest follow-up, laboratory tests showed CRP values ≤ 1.0 mg/L in 28/34 patients (mean 0.8 mg/L, range 0.0–1 mg/L); three patients with abnormal values had underlying rheumatological disorders, and three other had chronic urinary tract infections (two patients) or chronic leg ulcer (one patient). At X-ray examination, radiolucent lines around the implant were observed in four patients. No one underwent revision for aseptic loosening of the implant at the latest follow-up. No nail breakage was observed.

Discussion

This is, to our knowledge, the largest published series of patients treated with two-stage cementless modular nail without bone-to-bone fusion for chronically infected TKA. Results are consistent with those previously reported in a more limited series of patients treated according to a similar protocol [17]. Our data show that this treatment option may provide effective long-term infection control in nearly 90 % of patients and should be considered as a possible option among salvage procedures in failed, chronically infected TKA in which a more conservative approach is not possible or contraindicated or refused by the patient. In particular, in our series, at the time of surgery, all patients had one or more of the following conditions: periprosthetic infection due to multi-drug-resistant and highly virulent microorganism(s), severe bone loss, soft tissue defect, severe knee stiffness, deficit of the extensor knee apparatus, immunocompromised host, several failed surgeries previously and patient refusal of other surgical options.

In such cases, knee arthrodesis is reported as a possible solution; however, bone nonunion rates ranging from 4 % to

30 % have been observed, whereas healing time may take several months (Table 1). Whereas rigid fixation and compression generally contribute to successful arthrodesis, compression plating may be less reliable in patients with a failed TKA and who have osteopenic bone or infection. External fixation provides intra-operative compression but is also associated with a number of complications and drawbacks, including nonunion, limb shortening, pin-tract infection, long healing time, poor quality of life (QoL) during treatment, etc. [10, 12, 15, 18–20]. In 1948, Küntscher introduced a method for knee arthrodesis with an extra-long intramedullary nail extending from the greater trochanter to the tibial malleoli [27], and Knutson introduced the use of the Küntscher nail to treat failed knee arthroplasty, especially in patients who had marked bone loss [28]. This method offers good bending rigidity and the possibility of immediate postoperative weight bearing, being more comfortable for the patient than external fixation and allowing a high rate of bone fusion [29, 30]. In 2003, Christie et al. reported results of the first 54 patients treated with the Wichita fusion nail after revision TKA, for infection. In 53 knees, a solid fusion was demonstrated clinically and radiographically [31]. For these reasons this has been proposed as the procedure of choice by different authors to achieve bone fusion after failed infected TKA [8, 10, 13, 16, 28, 32, 33], even if the procedure is technically demanding, especially when a long, curved Küntscher nail is used, requiring long operative time and being associated with large blood loss; moreover, risk of nail breakage or migration has been reported, and limb-length discrepancy remains a frequent occurrence [10, 34].

Our experience shows that achieving bone-to-bone fusion may not be necessary in salvage procedures for failed infected TKA, whereas the use of a modular interlocking nail may allow early weight bearing, with a relatively low intra- and postoperative complication rate and stable clinical results in the long term. However, our data also point out that loss of

Table 1 Fusion rates with different surgical techniques

Author	Type of implant	No. of knees	Mean follow-up (months)	Fusion rate
Rand (1987)	Circular external fixator	28	3–12	71.4 %
Manzotti (2001)	Circular external fixator	6	34	83 %
Garberina (2001)	Circular external fixator	19	32	68 %
Oostenbroek (2001)	Circular external fixator	15	52	93 %
Klinger (2006)	Circular external fixator	18	48	89 %
Spina (2009)	Circular external fixator	17	30	76 %
Puranen (1990)	Intramedullary nail fixation Küntscher nail	33	38	87.8 %
Arroyo (1997)	Intramedullary nail fixation Küntscher nail	24	24	90 %
Christie (2003)	Intramedullary nail fixation Wichita nail	53	31	96 %
Crockarell (2005)	Intramedullary nail fixation Smith & Nephew	15	36	98 %
Talmo (2007)	Intramedullary nail fixation Biomet	29	48	82.7 %
Leroux (2013)	Intramedullary nail fixation Stryker T2	17	15	94.1 %

knee function is associated with an important impact on the patient's QoL and that the failure of a fixed knee prosthesis in these complex patients led to above-knee amputation in 50 % of cases. For this reason, this procedure should be restricted to a selected number of patients and proposed as a salvage procedure to be discussed with each patient, along with other possible options.

This study has some limits:

- The retrospective nature and the lack of a comparative series treated with other surgical approaches, including one-stage procedures or knee arthrodesis, do not allow us to draw any definitive conclusion concerning the best treatment method for patients in which this type of surgical option may be indicated.
- The relatively high proportion of patients with one or more comorbidities in our study may have an impact on the clinical result. However, the low numbers did not allow us to perform a multivariate analysis regarding the possible role of the different variables on the final outcome.
- Duration of antibiotic treatment and other important features of the protocol adopted in this case series are not based on scientifically proven evidence but on subjective and empiric evidence and thus may not be relevant to the final outcome.

In conclusion, this study provides evidence that two-stage, intramedullary, cementless nailing without bone-to-bone fusion may be a reliable salvage procedure for chronically infected TKA in a selected population of complex patients. It results in an acceptable long-term infection eradication rate, reduced pain and limb-length discrepancy and a relatively low surgical complication rate.

References

1. Goyal N, Miller A, Tripathi M, Parvizi J (2013) Methicillin-resistant *Staphylococcus aureus* (MRSA). Colonization and pre-operative screening. *Bone Joint J* 95B:4–9
2. Bozic KJ, Kurtz SM, Lau E, Ong K, Chiu V, Vail TP et al (2010) The epidemiology of revision total knee arthroplasty in the United States. *Clin Orthop Relat Res* 468:45–51
3. Montanaro L, Speziale P, Campoccia D, Ravaioli S et al (2011) Scenery of *Staphylococcus* implant infections in orthopedics. *Future Microbiol* 6:1329–1349
4. Trampuz A, Widmer AF (2006) Infections associated with orthopedic implants. *Curr Opin Infect Dis* 19:349–356
5. Kurtz S, Ong K, Lau E, Mowat F, Halpern M (2007) Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am* 89:780–785
6. Parvizi J, Zmistowski B, Adeli B (2010) Periprosthetic joint infection: treatment options. *Orthopedics* 33:659
7. Romanò CL, Gala L, Logoluso N, Romanò D, Drago L (2012) Two-stage revision of septic knee prosthesis with articulating knee spacers yields better infection eradication rate than one-stage or two-stage revision with static spacers. *Knee Surg Sports Traumatol Arthrosc*. doi:10.1007/s00167-012-1885-x
8. Conway DJ, Mont MA, Bezawada HP (2004) Arthrodesis of the knee. Current concepts review. *J Bone Joint Surg Am* 86-A:835–848
9. Nelson CL, Evarts CM (1971) Arthroplasty and arthrodesis at the knee. *Orthop Clin N Am* 2(2):245–264
10. Rand JA, Bryan RS, Chao EYS (1987) Failed total knee arthroplasty treated by arthrodesis of the knee using the Ace-Fischer apparatus. *J Bone Joint Surg* 69A:39–45
11. Damron TA, McBeath AA (1995) Arthrodesis following failed total knee arthroplasty: comprehensive review and meta-analysis of recent literature. *Orthopedics* 18:361–368
12. Oostenbroek HJ, VanRoermund PM (2001) Arthrodesis of the after an infected arthroplasty using the Ilizarov method. *J Bone Joint Surg Am* 83:50–54
13. Wiedel JD (2002) Salvage of infected total knee fusion: the last option. *Clin Orthop Relat Res* 404:139–142
14. Hanssen AD, Spanghel MJ (2004) Practical applications of antibiotic loaded bone cement for treatment of infected joint replacements. *Clin Orthop Relat Res* 427:79–85
15. Klinger HM, Spahn G, Schultz W, Baums MH (2006) Arthrodesis of the knee after failed infected total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc* 14:447–453
16. Talmo CT, Bono JV, Figgie MP, Sculco TP, Laskin RS, Windsor RE (2007) Intramedullary arthrodesis of the knee in treating sepsis after TKR. *HSSJ* 3:83–88
17. Iacono F, Bruni D, Lo Presti M, Raspugli G, Bondi A, Sharma B, Marcacci M (2012) Knee arthrodesis with a press-fit modular intramedullary nail without bone-on-bone fusion after an infected revision TKA. *Knee* 19:555–559
18. Spina M, Gualdrini G, Fosco M, Giunti A (2010) Knee arthrodesis with the Ilizarov external fixator as treatment for septic of knee arthroplasty. *J Orthop Trauma* 11:81–88
19. Garberina MJ, Fitch RD, Hoffmann ED et al (2001) Knee arthrodesis with circular external fixation. *Clin Orthop* 382:168–178
20. Manzotti A, Pullen C, Guerreschi F, Catagni MA (2001) The Ilizarov method for failed knee arthrodesis following septic TKR. *Knee* 8: 135–138
21. Neuerburg C, Bieger R, Jung S, Kappe T, Reichel H, Decking R (2012) Bridging knee arthrodesis for limb salvage using an intramedullary cemented nail: a retrospective outcome analysis of a case series. *Arch Orthop Trauma Surg* 132:1183–1189
22. Putman S, Kern G, Senneville E, Beltrand E (2013) Migaud H Knee arthrodesis using a customised modular intramedullary nail in failed infected total knee arthroplasty. *Orthop Traumatol Surg Res* 99(4): 391–398
23. Spanghel MJ, Masri BA, O'Connell JX et al (1999) Prospective analysis of preoperative and intraoperative investigations for the diagnosis of infection at the sites of two hundred and two revision total hip arthroplasties. *J Bone Joint Surg* 81:672–683
24. Lequesne M, Mery C, Samson M, Gérard P (1987) Index of severity for osteoarthritis of the hip and knee. *Scand J Rheumatol* 65:85–89
25. Joulie D, Girard J, Mares O, Beltrand E, Legout L, Dezeque H et al (2011) Factors governing the healing of *Staphylococcus aureus* infections following hip and knee prosthesis implantation: a retrospective study of 95 patients. *Orthop Traumatol Surg Res* 97:671–678
26. McPherson EJ, Woodson C, Holtom P, Roidis N, Shufelt C, Patzakis M (2002) Periprosthetic total hip infection. Outcomes using a staging system. *Clin Orthop Relat Res* 403:8–15
27. Kuntscher GBG (1948) Recent advances in the Field of Medullary Nailing. *Ann Chir Gynaecol Fenniae* 37:115–136
28. Knutson K, Lindstrand A, Lidgren L (1984) Arthrodesis for failed knee arthroplasty: A nationwide multicenter investigation of 91 cases. *Clin Orthop* 191:202–211

29. Puranen J, Kortelainen P, Jalovaara P (1990) Arthrodesis of the knee with intramedullary nail fixation. *J Bone Joint Surg Am* 72:433–442
30. Arroyo JS, Garvin KL, Neff JR (1997) Arthrodesis of the knee with a modular titanium intramedullary nail. *J Bone Joint Surg Am* 79:26–35
31. Christie MJ, DeBoer DK, McQueen DA, Cooke FW, Hahn DL (2003) Salvage Procedures for failed Total Knee Arthroplasty. *J Bone Joint Surg* 85-A(1):58–62
32. Wilde AH, Stearns KL (1989) Intramedullary fixation for arthrodesis of the knee after infected total knee arthroplasty. *Clin Orthop* 248:87–92
33. Crockarell JR, Mihalko MJ (2005) Knee arthrodesis using an intramedullary nail. *J Arthroplasty* 20:703–708
34. Donley BG, Matthews LS, Kaufer H (1991) Arthrodesis of the knee with an intramedullary nail. *J Bone Joint Surg Am* 73:907–913