Original Article

Results of titanium locking plate and stainless steel cerclage wire combination in femoral fractures

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Abstract

Background: Some *in vitro* studies warn combining different metals in orthopedic surgery. The aim of this study is to determine the impact of combining titanium and stainless steel on bone healing and the clinical course of patients undergoing internal fixation of femoral fractures.

Materials and Methods: 69 patients with femoral fractures had polyaxial locking plate osteosynthesis. The locking plate was made of a titanium alloy. Two different cohorts were defined: (a) sole plating and (b) additional stainless steel cerclage wiring. Postoperative radiographs and clinical followup were performed at 6 weeks, 3 months and 12 months.

Results: Cohorts A and B had 36 and 33 patients, respectively. Patient demographics and comorbidities were similar in both groups. In two cases in cohort A, surgical revision was necessary. No complication could be attributed to the combination of titanium and stainless steel.

Conclusion: The combination of stainless steel cerclage wires and titanium plates does not compromise fracture healing or the postoperative clinical course.

Key words: Cerclage wire, fracture healing, galvanic corrosion, locking plate, titanium, stainless steel

Introduction

Femoral fractures, especially spiral fractures or those after stemmed arthroplasty, often need cerclage wire fixation to optimize the reduction of plate osteosynthesis. Till date, state-of-the-art implants for plate osteosynthesis are made of titanium alloy.[1,2] Cerclage wires made of stainless steel have the best biomechanical properties, are easy to use and are reliable for internal fixation and offer sufficient stability.[3-5] Alternative devices such as cable buttons and others made of cobalt-chrome or titanium alloy are insufficient for strength and stability.[4,5]

It has been postulated that one should not combine implants of different metals in orthopaedic devices.[6,7] The AO Foundation mentions: ''Mixing of stainless steel implants with unalloyed titanium, titanium alloy and cobalt alloy implants should be avoided for implants that are in contact with each other,''[8] without presenting corroborating evidence.

Both stainless steel and titanium are corrosion resistant due to a passivizing protective oxide layer which quickly forms on the surface. Titanium is regarded as the more corrosion resistant metal of the two, as stainless steel is more susceptible to surface corrosion phenomena. However, gray or black discoloration in the soft tissue adjacent to titanium implants is commonly found in clinical settings and is attributed to wear and tear.[9,10] Some laboratory studies have demonstrated that most materials coupled with implant quality stainless steel are clinically unsafe.[11,12] However, some studies have failed to show increased corrosion when titanium and stainless steel are combined.[13,14] Moreover, medicolegal issues arise in cases of delayed fracture healing or other complications and have not been clearly addressed.

The aim of this study is to determine the impact of combining titanium and stainless steel on bone healing and the clinical course of patients undergoing internal fixation of femoral fractures.

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Materials and Methods

Standardized prospective data collection of all femur fractures treated by minimally invasive internal fixation with a polyaxial locking plate (NCB-DF®) was performed. This study was approved by our institutional ethics committee (reference no. 110/10). Most fractures were in the metaphyseal area.

Two groups of patients were compared. Cohort A consisted of all patients with solely titanium alloy plate fixation. Cohort B consisted of all patients who received additional stainless steel cerclage wires. Preoperative mobility and intraoperative parameters i.e. surgery time, blood loss, image intensifier time etc., were recorded. Clinical followup was performed at 6 weeks, 3 months and 12 months and included evaluation of wound healing, functional assessment, bony consolidation (both cortices bridged, fracture line no longer evident, no pain at loading), the Glasgow Outcome Scale (GOS)[15] and the general complications of osteosythesis [Table 1]. The GOS was used to compare activities of daily living (ADL) pre and postoperatively. To facilitate ease of comprehension, the GOS was inverted (1 = good recovery and 5 = death).[16]

All fractures were reduced and fixed using the titanium alloy polyaxial locking Non-Contact-Bridging-plate Distal-Femur (NCB-DF® Zimmer Inc., Winterthur, Switzerland, CE-No. PSI 0086, product no. 02.03260.),[17] a device composed of commercially pure titanium (cp Ti). One important feature is the opportunity for minimally invasive implantation via the aiming device, which follows the principles of biological osteosynthesis, preserving biology of the fracture region. Cerclage wires (Synthes, Oberdorf, Switzerland article number 291.060) are made of stainless steel delivered in a 10 m coil with a diameter of 1.25 mm.

Indications and operative procedure

Primary fractures were stratified according to the AO classification, while periprosthetic fractures were based on the Vancouver classification[18] for the proximal femur and the Rorabeck classification[19] for the distal femur.

Table 1: Modified Glasgow outcome scale

GOS 1	Good recovery
GOS 2	Moderate disability (disabled but independent), no assistance with activities of daily living
GOS 3	Severe disability (conscious but disabled), needing assistance with activities of daily living
GOS 4	Persistent vegetative state
GOS 5	Death

GOS = Glasgow outcome scale

For fracture stabilization, two operative techniques were defined. The "mini-open" approach was indicated for two-part long spiral fractures. The "minimally invasive" approach was used for all other fracture types, primarily multi-fragmented or short oblique fractures. The main concept in both techniques was closed reduction. This was achieved by either ligamentotaxis and/or the application of the plate as a template. In the "minimally invasive" concept, the plate was inserted through a short (8 cm) incision [Figure 1]. By setting the shaft screws first, the plate was used as a reduction tool. After control of the axis, length and rotation, the plate was fixed distally. The screws were locked with a cap when correct reduction and plate position was accomplished, leading to locking by friction and polyaxial stability. In the "mini-open" technique [Figure 2], open reduction and temporary fracture fixation were performed before the plate was inserted. For this step, an incision at the level of the plate insertion was made that was sufficient to expose the fracture region. The two fragments were reduced with forceps until optimal contact with anatomical alignment of axis and rotation was achieved. The forceps were then replaced by cerclage wire(s). Then, the plate was inserted with the jig and fixed as described above.

69 NCB-DF® surgeries were performed. All patients were successfully evaluated at all followup points. Cohort A consisted of 36 patients (mean age 68 years, range 17-94 years; 19 left sided, 17 right sided; mean American Society of Anesthesiologists (ASA) score 2.6, range 1-4). A total of 19 patients had osteoporosis (as measured by DEXA), osteomalacia or pathological bone disorders. A total of 21 fractures followed arthroplasty or peri-implant fractures. In 15 patients, NCB-DF® osteosynthesis was performed after femoral fracture as the primary treatment.

Cohort B consisted of 33 patients (mean age 78.9 years, range 43-99 years; 15 left sided, 18 right sided; mean ASA score 2.8, range 2-4). A total of 22 patients had underlying bone disease (osteoporosis, osteomalacia, or another

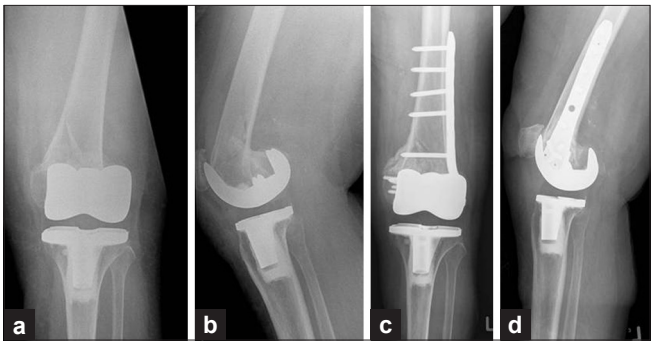

Figure 1: (a) Anteroposterior and (b) lateral view showing Rorabeck Type 2 periprosthetic fracture, (c,d) Postoperative anteroposterior and lateral view showing reduction in minimal invasive technique with NCB

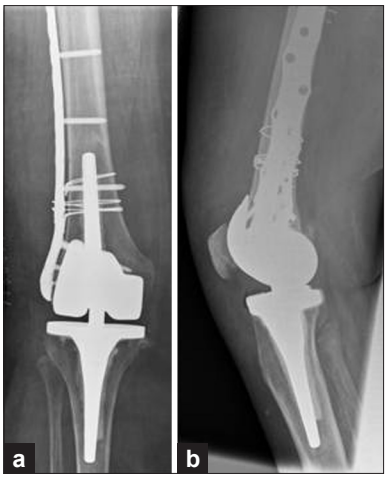

Figure 2: (a) postoperative anteroposterior and (b) lateral view showing a Rorabeck type 2 spiral fracture fixed with "mini-open"-technique with cerclage wires and NCB

pathological bone disorder). A total of 25 fractures occurred after arthroplasty or implant insertion. In eight patients, NCB-DF® osteosynthesis was performed after femoral fracture as the primary treatment.

In the followup period, two patients (aged 86 and 87 years) in Cohort A died 1 and 5 months after discharge due to cardiac insufficiency. In Cohort B, five patients (aged 84-99 years) died in the same period, not associated with implant insertion, over a 1-6 month period.

A total of 28 patients in Cohort A completed followup to 12 months in person. In five patients, followup was performed by telephone. Two patients died and one was lost to followup. In Cohort B, 21 patients completed followup to 12 months in person. In six cases, followup was performed by telephone. Five patients died and one was lost to followup. Followup in person was declined by 5 patients in Cohort A and 6 patients in Cohort B due to advanced dementia or immobility. In five Cohort B patients who underwent telephone followup, external X-rays were performed and evaluated.

Statistical analysis

Descriptive analysis of values was performed and the mean and standard deviation calculated. All calculations were performed using the SPSS and R statistical software (version 2.12.1; http://www.r-project.org).

Results

In Cohort A, surgery time was 102.4 (range 40-173) min) compared to 113.5 (range 43-197) minutes in Cohort B. Intraoperative image intensifier time was 2.7 min (range 0.27-5.25) minutes in Cohort A and 3.1 (range 1.2-5.4) minin Cohort B. Intraoperative blood loss as measured by intraoperative transfusion was on average 0.9 (range 0-4) blood bottles (BB) for each 500 ml per patient in Cohort A compared to 1.4 (range 0-6) BB per patient in Cohort B. In Cohort B, an average of 1.6 cerclage wires per surgery were required (18 × one cerclage wire, 8 × two cerclage wires, 7 × three cerclage wires). The rehabilitation program was standardized in both cohorts, with no weight bearing on the affected extremity for 6 weeks.

In Cohort A, 12 month-followup X-rays showed complete bony consolidation without secondary loss of reduction in 24 patients. In these patients, function of the knee joint at that time was sufficient (ROM ≥ 0-0-90°). One patient showed a 15° valgus malalignment, a second had an internal rotation deficit of 10° with leg shortening of 2 cm. This was due to primary suboptimal reduction and fixation, but without any functional consequence as these patients were mobilising on orthopaedic device assistance preoperatively.

In Cohort B, followup X-rays showed complete bony consolidation in the correct axis without secondary loss of reduction in 24 patients and sufficient knee joint function (ROM ≥ 0-0-90°). Two patients presented with suboptimal reduction (1 × medial displacement of distal fragment, 1 dorsal displacement of distal fragment) without much consequences due to the general condition of these patients. No cerclage wire failure or breakages were observed.

No differences in the period of union rates were seen between the both groups. The GOS at 12 months followup for Cohort A increased by 3 points in 1 patient, by 1 point in 10 patients and went to baseline in 24 patients. For Cohort B, the GOS course increased by 3 points in 3 patients, by 2 points in 3 patients, by 1 point in 9 patients and went to baseline in 17 patients.

Complications

Complications were divided into "need for revision" and "no need for revision." General complications with "no need for revision" included one deep vein thrombosis in each cohort, treated conservatively. A total of 15 patients in Cohort A developed general complications: In patients had primary suboptimal fracture reduction. Revision was not indicated in view of low mobility requirements in these patients. In Cohort B, 23 patients had general complications without surgical consequences; three were due to surgical technique. Two patients presented with suboptimal reduction. One patient had a femoral nerve lesion, which recovered completely in 5 months.

Two patients in Cohort A developed complications with a "need for revision:" The fracture extent was preoperatively underestimated, resulting in an early change of too short

metaphyseal screws a few days after the primary surgery. No patient developed perioperative infection.

Demographics and comorbidities were similar in both patient cohorts. Statistical evaluation of the above mentioned data showed significant differences only in age with no statistical analysis in the ASA classification of both cohorts, demonstrating that patients of Cohort A were about 10 years younger and had less comorbities than patients in Cohort B. Observing differences in duration of surgery, a mean difference of nearly 11 min between both cohorts was found, which was statistically not significant. Similar results could be seen when comparing blood loss. In Cohort B, the mean transfusion amount was nearly 50% higher than in Cohort A, with no statistical significance. All other measured parameters showed no statistically significant difference between the groups. The detailed statistical evaluation is shown in Table 2.

Discussion

In this study, two cohorts with similar fracture etiology were collectively investigated for the effect of mixing titanium alloy plates and stainless steel cerclage wires on femoral fracture healing and clinical course. The followup period was limited to 12 months, as these surgeries were performed in elderly patients and were evaluated for early complication rates and reintegration into the pretrauma environment. Within this period, fracture healing was evaluated.[20] In a recent study, it was determined that the average time for healing of distal femoral fractures can be up to 15 weeks.[20] Recent studies show no long term results for this group of patients. In the present study, long term followup (including telephone surveys) was more than 90%.

Demographics and comorbidities were similar in both patient cohorts. The higher age of patients in Cohort B could be related to the fracture entity. With increasing age, medical comorbidities also increase, as well as the likelihood of having a fracture around an implant. Moreover, longer ICU stays (average 11 hours) in Cohort B patients is concordant with higher age and higher ASA score. Surgeries in Cohort B lasted an average of 11 min longer. This was due to the need of additional cerclage wire fixation. In Cohort B, blood loss was 50% higher due to a more extensive surgical approach, carrying a higher risk of injuring perforating veins. Cerclage wire fixation led to more X-ray time as well, but both comparison points failed to demonstrate statistical significance. Concerning clinical outcome measured with the GOS, no statistical differences were shown at the 12 month followup visit. In summary, no complications or surgical revisions could be related to the combination of stainless steel wires and titanium alloy plates.

Few studies dealing with NCB-DF® plates and combination with stainless steel cerclage wires are published. Erhardt *et al.* presents osteosynthesis of 24 periprosthetic fractures, showing a reoperation rate of 15% and a healing rate of 90%.[17] In this

Table 2: Statistical evaluation

	Cohort A NCB (control) *n*=36	Cohort B NCB+Cerclage *n*=33	Significance (*P* value)
Age	68.00 years±21,03	78.94 years±11,99	Significant *P*<0.05
ASA-score	2×1 14×2 16×3 4×4	0×1 7×2 25×3 1×4	n.s. *P*=0.059
No. of patients with bone disease (e.g., osteoporosis)	19	22	n.s.
No. of patients with fracture around an implant	21	25	n.s.
duration of surgery	102.44 min. ± 43.4	113.50 min. ± 38.50	n.s.
Blood loss (Blood bottle transfusion @ 500 ml)	0.86 BB±1.48	1.42 BB±1.66	n.s.
Image intensifier time	2.65 min. ± 1.54	3.15 min. ± 1.37	n.s.
ICU stay	31.54 h±44.84	42.75 h±72.86	n.s.
Glasgow outcome score pre/No. of patients	11×1 17×2 8×3	3×1 21×2 9×3	n.s.
Comparison of glasgow outcome score pre and at 12 months	24 same 11 worse	17 same 15 worse	n.s.

ICU = Intensive Care Unit, ASA = American Society of Anesthesiologists, NCB = Non-Contact Bridging Plate

study, reduction of large fragments was performed if necessary by isolated interfragmentary cortical screws (3.5 mm) away from the plate. Only two patients required additional stainless steel cerclage wires. No complications were reported due to the mixing of materials. Pressmar *et al*.[8] reported on 11 revision surgeries out of 31 NCB-DF® implantations with a total of 20% implant failures. In his study, eight patients received additional stainless steel cerclage wires. However, these authors did not relate any of their complications to the mixing of different metals.

Comparing this data to results of monoaxial locking titanium alloy plates (LISS or LCP), there was no negative influence of accompanying stainless steel cerclage wiring and comparable or lower complication and revision rates were reported.[21-24]

Orthopaedic surgeons often have no other choice but to combine steel cerclage wires with titanium alloy plates as they lack sufficient stable titanium alloy tension wires. Manufacturers of surgical devices do not recommend combining different metals, putting the complete responsibilityand liability of possible complications on the surgeon. In the present study, all patients reached complete bony consolidation at radiologically stable implants (plates and cerclage wires).

To conclude, combination of titanium alloy locking plates and stainless steel cerclage wires in minimally invasive closed reduction and internal fixation of femoral fractures did not show any negative effects on fracture healing or the clinical course, compared to controls. Till date, there is no clinical evidence for not combining titanium alloy plates and stainless steel wires.

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