Tricortical Versus Quadricortical Syndesmosis Fixation in Ankle Fractures

A Prospective, Randomized Study Comparing Two Methods of Syndesmosis Fixation

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Objective: To assess short-term functional results in 2 types of syndesmotic fixation, comparing the traditional rigid quadricortical syndesmotic screw fixation with a more dynamic tricortical screw fixation.

Design: Prospective, randomized clinical study.

Setting: University clinic, level 1 trauma center.

Patients: Sixty-four patients with closed ankle fractures in which the syndesmosis was found to be unstable intraoperatively.

Intervention: The unstable syndesmoses were fixed with either one 4.5-mm cortical screw through both tibial cortices (n = 30) or two 3.5-mm cortical screws engaging only 1 cortex of the tibia (n = 34). The quadricortical screws were routinely removed after 2 months, whereas the tricortical screws were removed only in the case of discomfort. Rehabilitation was the same in both groups.

Results: The Olerud Molander functional score (0–100) was significantly higher in the tricortical group (77 points) compared with the quadricortical group (66 points) ($P = 0.025$) at 3 months. After 1 year, however, the functional score was not significantly higher ($P = 0.192$) in the tricortical group (92.6 points) compared with the quadricortical group (85.7 points). Pain was significantly lower in the tricortical group ($P = 0.017$) after 3 months, but there was no significant difference after 1 year. There was no significant difference in dorsiflexion between the groups at any point of time. No losses of fixation were detected. The tricortical screws were removed in 2 patients due to migration.

Conclusions: Syndesmosis fixation with 2 tricortical screws is safe and improves early function. After 1 year, however, there were no significant differences between the 2 groups in functional score, pain, and dorsiflexion.

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The use of a cortical screw with bicortical holds in the tibia (quadricortical screw) has traditionally been the recommended fixation for a ruptured syndesmosis in ankle fractures.[1] Removal of the quadricortical screw is usually performed 8 to 12 weeks after insertion,[1] which generally implies 2 to 6 extra weeks of partial weight bearing after the fracture has healed. However, early motion of injured joints is generally recommended, as prolonged immobilization may lead to joint stiffness and loss of function.[2] There is furthermore a risk for surgical site infection following removal, albeit small.

Heim et al recommended the use of a syndesmosis screw with only 1 cortical hold in the tibia (tricortical screw) without the need for screw removal prior to full weight bearing.[3] They found spontaneous loosening in 91% of the patients with tricortical screws, indicating that micromotion of these screws make them more likely to loosen rather than to break. Cadaver studies have demonstrated that rigid fixation of the syndesmosis affects ankle biomechanics unfavourably.[4,5] However, a tricortical syndesmosis screw with only 1 cortical hold in the tibia may not completely fix the syndesmosis joint, allowing some movement during ankle motion. Spontaneous loosening and resorption of the bone surrounding the screws may reestablish normal motion within the syndesmosis, thus making routine removal of the tricortical syndesmosis screws unnecessary.

Theoretically, 2 tricortical syndesmosis screws with the same number of cortical holds in the tibia as 1 quadricortical screw may produce sufficient fixation. However, no biomechanical studies exist to support these assumptions, and no prospective randomized comparative studies exist to conclude what method of syndesmosis fixation is preferable.

We questioned whether fixation of the syndesmosis using 2 tricortical screws would provide sufficient holding

strength without the need for screw removal before full weight bearing. Our test hypothesis was that there was no difference in function, dorsiflexion, or loss of reduction when comparing the groups after 3 months and 1 year. To test this hypothesis, we performed a prospective, randomized study comparing one 4.5-mm quadricortical screw with two 3.5-mm tricortical screws.

MATERIALS AND METHODS

A prospective randomized comparative trial was conducted during a period of 20 months in 1998 and 1999 on 64 patients with an acute ankle fracture for which transsyndesmotic fixation was indicated. Institutional review board approval was achieved prior to implementation of the study. Randomization was performed, open-labeled, by drawing closed, randomly mixed envelopes from blocks of 40 and 30. Enrollment stopped after 64 patients according to a predetermined time limit after the number of included patients had exceeded 60. Sample size was estimated based on a power requirement of minimum 80%, estimated standard deviations,[6] expected dropouts (20%), and a difference in the functional outcome score assumed to be of clinical interest (15%). The study was performed according to an intention-to-treat protocol.

The groups were comparable with respect to demography, fracture types, primary soft-tissue injuries, mechanism of trauma, and concomitant diseases (Table 1). Patients admitted with an acute ankle fracture as a single orthopaedic injury were evaluated for inclusion. If a bimalleolar or trimalleolar injury and displacement of more than 2 mm in any plane on the radiographs[7] was present, open reduction and internal fixation was generally indicated, and the patients were asked to participate in the study (Fig. 1). One hundred thirteen patients gave their written consent on a consent form. Sixty-four patients with AO type C fractures and/or pathologic widening of more than 2 mm of the syndesmosis at intraoperative testing with a hook following fixation of the fractures[8] were randomized to either two 3.5-mm tricortical syndesmosis screws (tricortical group, n = 34) or one 4.5-mm quadricortical syndesmosis screw (quadricortical group, n = 30). The quadricortical screw was placed 2 to 3 cm proximal to the ankle joint, as was the distal tricortical screw. The second tricortical screw was placed 1 to 2 cm proximal to the distal screw. If the plate was placed in the syndesmotic area, the screws were placed though the neighboring holes in the plate (Figs. 2, 3).

On admission, complete demography, concomitant diseases, injury description, and chronology were registered on a standardized form that followed the patients throughout the study. The state of the soft tissues around the ankle was classified according to Tscherne and Gotzen.[9]

The fractures were classified according to AO based on all available lateral, frontal, and mortise radiographs and computed tomography (CT) scans.[10] A deltoid ligament rupture was diagnosed if the medial tibiotalar clear space was more than 5 mm or exceeded 3 mm compared to the lateral talofibular clear space.[6] The patients were treated according to the recommendations of the AO/ASIF group.[1] Severely dislocated fractures were adequately reduced on admission. All patients received immobilization treatment by plaster or traction and elevation until surgery. Patients who were not operated on within 6 to 8 hours were in general operated on after 5 to 7 days of immobilization. Prophylactic antibiotics (cephalothin 2 g)

TABLE 1. Demography, Trauma Mechanisms, and Concomitant Diseases

	Quadricortical Group (n = 30)	Tricortical Group (n = 34)	Difference
Women:men	13:17	19:15	NS
Age (SD)	41.8 (17.9)	42.4 (14.7)	NS
Weight (SD)	82.7 (15.2)	78.2 (16.3)	NS
Height (SD)	174.8 (10.0)	173.9 (9.9)	NS
AO fracture type B	15	14	NS
AO fracture type C	15	20	NS
Tscherne type 1 soft-tissue lesions on admittance	1	2	NS
Fall at the same level	21	24	NS
Fall from a height	1	2	NS
Sports accidents	8	7	NS
Road traffic accidents	0	1	NS
Alcohol abuse	0	3	NS
Diabetes	1	1	NS
Daily cigarette smoking	4	10	NS

Any statistically significant difference between the groups is noted in the far right column (S, significant; NS, not significant).

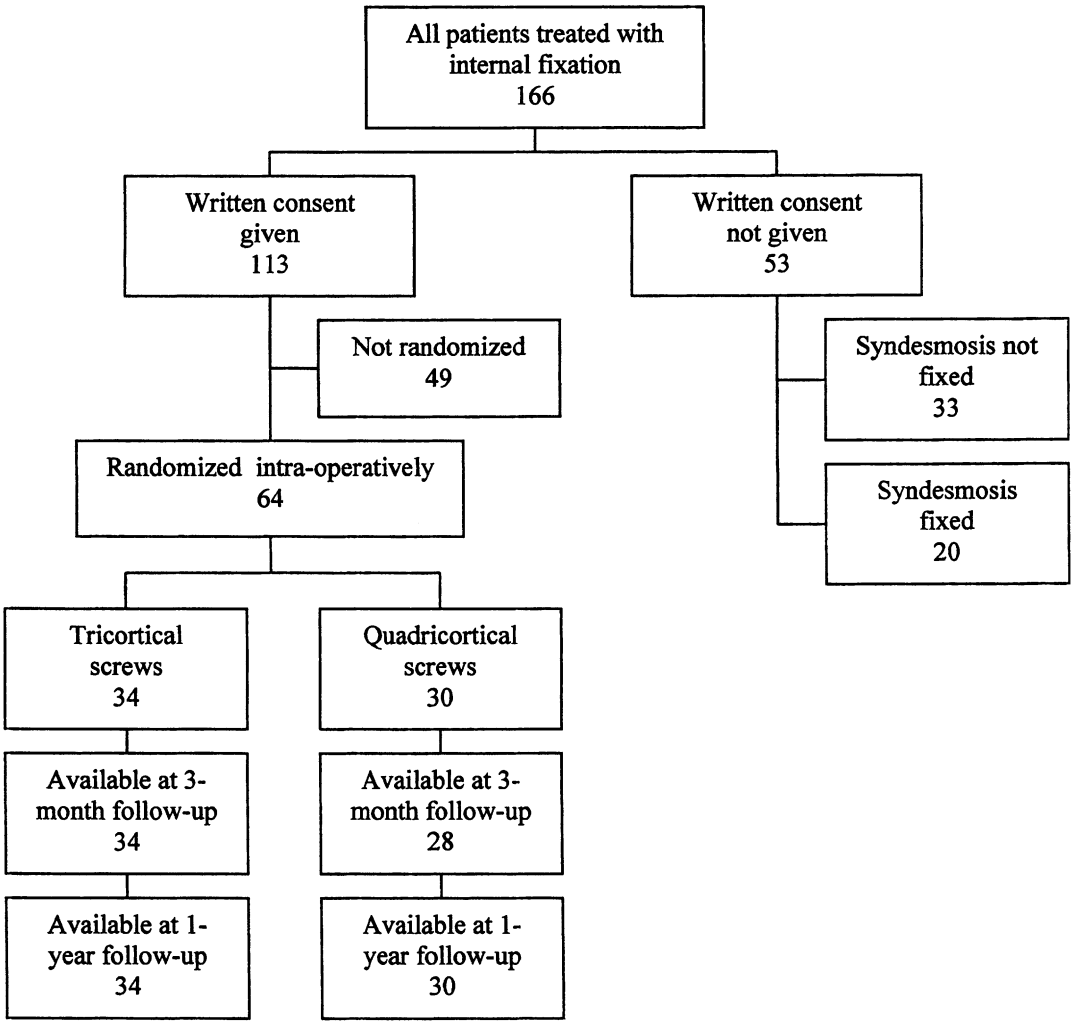

FIGURE 1. Overview of all patients evaluated for inclusion in the study.

and thromboembolic prophylactics with low molecular heparin (dalteparin) were routinely administered. Ruptured deltoid ligaments were not repaired.[11] Postoperatively, the ankle was immobilized for 2 to 3 days, then the patients were allowed careful movement and 2 to 5 kg weight bearing as instructed by a physiotherapist until the 6-week follow-up.[12] Patients randomized to quadricortical syndesmosis fixation were not allowed full weight bearing until the screw was removed after 8 to 12 weeks. Patients randomized to tricortical syndesmosis fixation were allowed full weight bearing after 8 weeks. According to the study protocol, tricortical screws were removed only if there was no sign of bony resorption around the screw holds in tibia on the radiographs combined with inexplicable pain at the 3-month check-up, thus indicating rigid fixation of the syndesmosis.

To control the adequacy of the placement of the syndesmosis positioning screw(s), a CT scan was performed before full weight bearing was allowed, usually 4 to 5 weeks after surgery. Revision osteosynthesis was considered in the case of postoperative displacement more than 2 mm combined with excessive pain at the 6-week check-up.

Clinical checkups with radiographs, interviews, and examinations were in all cases performed by the primary author after 6 weeks, 3 months, and 1 year according to standardized forms. The radiographs were routinely examined by an independent radiologist.

Dorsiflexion was assessed under loaded conditions as described by Lindsjö et al[13]; the angle between the floor and a line drawn from the fibular head to the lateral malleolus was measured while the patient was sitting on a 10-inch-high stool with the knee flexed, forcing the ankle into maximal dorsiflexion with the heel in firm contact with the floor. The difference in dorsiflexion between the fractured and nonfractured ankle was used for statistical evaluation. To control consistency of the measurements, intraclass correlation coefficient (ICC) was calculated based on measurements of the unaffected ankle at 3 months and 1 year.

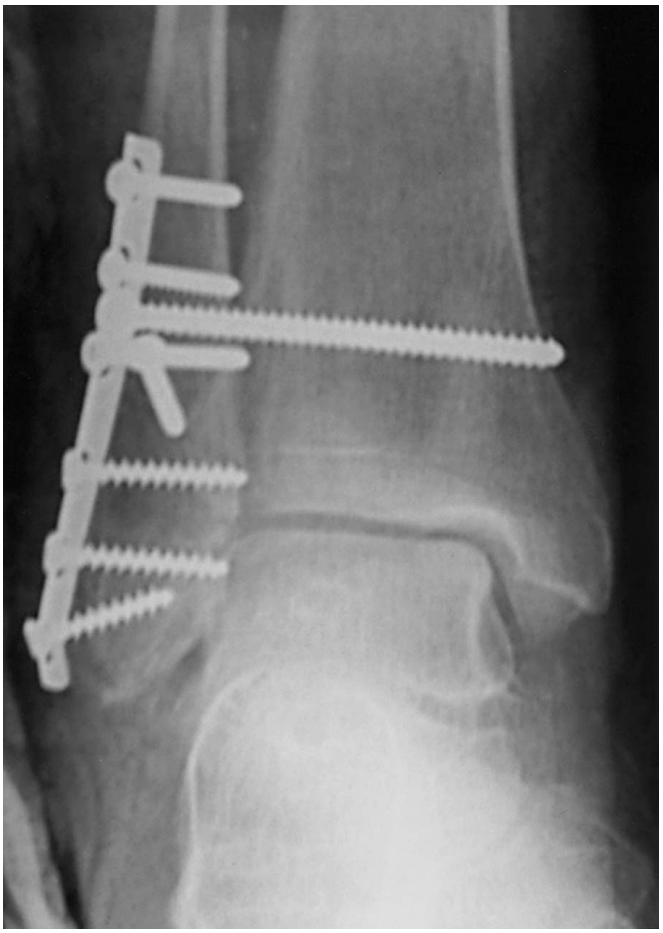

FIGURE 2. The quadricortical syndesmosis screw holds all 4 cortices of fibula and tibia. The screw keeps fibula rigidly fixed to tibia. The patient is allowed partial weight bearing and movement therapy until screw removal at 8 to 12 weeks postoperatively. As expected, there are no signs of loosening in this case at 6 weeks postoperatively.

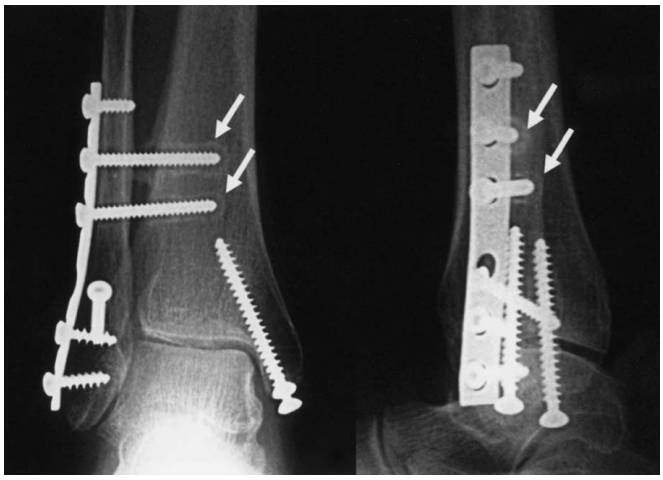

FIGURE 3. Example of tricortical screw fixation from this study. The screws hold only 1 cortex in the tibia, allowing some movement in the horizontal plane. There is spontaneous loosening with bony resorption around the screws (arrows) in the tibia after 1 year.

The subjective functional score described by Olerud and Molander[14] was used to evaluate patient satisfaction and function (Table 2).[15]

Radiographs of both ankles were performed at the 1-year check-up in the lateral, anteroposterior (AP), and mortise views for evaluation of displacement and posttraumatic osteoarthritis according to the modified criteria of Magnusson[16] (Table 3).

Evaluation of the success of reduction postoperatively and at follow-ups depended on the position of talus on standard AP and lateral radiographs and the position of a posterior malleolus fragment in the lateral view. A displacement of 2 mm or less in any projection was considered acceptable. In the case of an intact or undisplaced medial malleolus, displacement was diagnosed if the medial tibiotalar clear space was more than 5 mm or exceeded 3 mm compared with the talofibular joint space.[6] Polytrauma was defined as an isolated ankle fracture plus other organ system injury and an Injury Severity Score more than 15.[17] High-energy trauma was defined as motor vehicle accidents, fall from more than 5 meters, and crush injuries. Surgical site infections were defined according to the criteria of Centers for Disease Control and Prevention.[18]

Statistical evaluation was performed using SPSS 10.0 for Windows. The significance level was set to 0.05 and all tests were 2-sided. *P* values were not adjusted for multiple testing.

RESULTS

All patients attended the 3-month follow-up except 2 patients in the tricortical group. All patients attended the 1-year follow-up.

At the 3-month follow-up, the patients in the tricortical group scored higher on all functional parameters and the overall functional score was significantly higher (10.7 points) ($P = 0.025$, confidence interval [CI] 1.4–20.0, independent samples *t* test). The patients in the tricortical group had significantly less pain ($P = 0.017$, CI 0.8–7.5, independent samples *t* test) at this point, but there was no significant difference after 1 year.

At the 1-year follow-up, the difference in the functional score between the groups was 5.5 points in favor of the tricortical group ($P = 0.192$, CI 2.8–13.8, independent samples *t* test). However, the patients in the tricortical group scored higher on all functional parameters, except for jumping (Table 2).

Dorsiflexion was significantly better in the nonfractured ankles compared with the fractured ankles after 3 months ($P < 0.001$, CI 10.3–15.7, paired samples *t* test) and 1 year ($P < 0.001$, CI 5.1–8.8, paired samples *t* test) (Table 4).

The difference in dorsiflexion between the fractured and the nonfractured ankle after 3 months was in average 2.8° bet-

TABLE 2. Olerud Molander Subjective Functional Score

	Range	Tricortical Group 3 Months	Quadricortical Groups 3 Months	Tricortical Group 1 Year	Quadricortical Group 1 Year
Pain	0–25	23.0 (4.0)	18.8 (8.3)	23.5 (4.5)	22.3 (5.7)
Stiffness	0–10	5.0 (5.1)	3.7 (4.9)	6.2 (4.9)	5.0 (5.1)
Swelling	0–10	4.8 (2.7)	4.5 (3.6)	7.9 (3.3)	6.8 (3.1)
Stairs	0–10	7.8 (2.5)	6.8 (2.8)	9.1 (1.9)	8.3 (2.4)
Running	0–5	2.5 (2.5)	1.5 (2.3)	4.3 (1.8)	3.8 (2.2)
Jumping	0–5	3.9 (2.1)	3.5 (2.3)	4.4 (1.6)	4.5 (1.5)
Squatting	0–5	3.6 (2.3)	3.0 (2.5)	4.6 (1.4)	4.2 (1.9)
Support	0–10	8.9 (3.0)	8.0 (3.9)	9.7 (1.7)	9.7 (1.8)
Activity	0–20	17.5 (2.8)	16.3 (3.5)	19.1 (2.3)	18.7 (2.2)
Total	0–100	77.0 (16.1)	66.3 (20.1)	88.8 (14.6)	83.3 (18.6)

A score less than 100 indicates loss of function. All values are no. (SD).

ter in the tricortical group ($P = 0.296$, CI −0.43–10.9, independent samples t test). After 1 year, the difference was 1.3° greater in the tricortical group than the quadricortical group ($P = 0.493$, CI −2.6–5.2, independent samples t test).

The quadricortical syndesmosis screws were removed on average at 9.5 weeks (SD ±1.4) after surgery. There was no indication for removal of any of the tricortical screws at this point, as none of the patients complained of inexplicable pain.

Two Tscherne type 1 lesions were found in the tricortical group versus 3 type 1 and 1 type 2 in the quadricortical group.

Complications were equally distributed within the groups (Table 5). No other complications, such as pneumonia or deep venous thrombosis, were found in either group.

All fractures healed clinically and radiographically within the 3-month follow-up. After 1 year, slight displacement beyond 2 mm was found in 5 patients in the quadricortical group and in 1 patient in the tricortical group ($P = 0.090$, Fisher exact test). These patients had painless good function, and revision osteosynthesis was therefore not performed. Slight reduction of joint space (<50%) was noted at the 1-year follow-up in 4 patients in the tricortical group and in 5 patients in the quadricortical group, of which slight displacement was concurrently found in 2 patients. Postoperative CT scans demonstrated malreduction of the syndesmosis in 2 patients. Due to concomitant severe pain, these patients underwent revision surgery and refixation of the syndesmosis using the same syndesmosis screws. Both fractures healed uneventfully. Acceptable placement of the syndesmosis screws were found in all but 1 patient in whom the tricortical screws were too long, thus providing quadricortical holds. These screws showed no signs of loosening and were thus removed 3 months postoperatively because the joint was stiff and painful. No patients were, however, withdrawn from the study.

Fractured tricortical syndesmosis screws (n = 5) were not removed, as there was no apparent discomfort. Three tricortical syndesmosis screws were removed in 2 patients due to spontaneous loosening and telescoping after 3 months. No infections occurred after screw removal in either group.

TABLE 3. Osteoarthritis as Assessed on Lateral and Mortise Radiographs Compared to the Uninjured Side

No OA	Normal talocrural joint space
1st degree:	<50% narrowing of talocrural joint space
2nd degree:	>50%
3rd degree:	Bone-to-bone contact
4th degree:	Bone loss

OA, osteoarthritis.

DISCUSSION

The main purpose of this study was to investigate any possible difference in early joint movement and function after syndesmosis fixation with 2 different methods. Secondly, we aimed to investigate whether tricortical fixation of the syndesmosis—without the need for screw removal—was adequate.

As the syndesmosis may be regarded as being part of the ankle joint, and as early movement of joints after injury traditionally has been advocated as beneficial, it seems reasonable to apply the same philosophy in the case of a rupture of the syndesmosis joint (Fig. 2).

Michelson and Waldman found no change in coupled motion of the ankle when tricortical syndesmosis screws were used.[19] It is therefore reasonable to assume that tricortical fixation of the syndesmosis acts as a more dynamic type of fixation, allowing less constrained motion of the ankle joint until healing of the bony and ligamentous injuries, in particular rotational motion (Fig. 3).

TABLE 4. Dorsiflexion

	Quadricortical Group (n = 30)	Tricortical Group (n = 34)	*P*	Significant
Df normal ankle at 3 mos	43.6° (9.4)	39.6° (7.1)	0.063	No
Df fractured ankle at 3 mos	29.2° (8.7)	28.0° (7.9)	0.573	No
Df normal ankle at 1 yr	43.1° (7.6)	40.1° (7.3)	0.115	No
Df fractured ankle at 1 yr	35.5° (7.9)	33.8° (6.8)	0.375	No

T tests have been performed. Values are no. (SD).
Df, dorsiflexion.

The holding strength necessary to transfix the syndesmosis after an injury is not known and will vary from case to case depending on the severity of the injury. Xenos et al reported superior fixation strength using 2 quadricortical screws compared with 1 quadricortical screw.[20] Thus, the number of cortical holds is likely to reflect the fixation strength. Thompson and Gesink found no biomechanical differences comparing one 3.5-mm cortical screw with one 4.5-mm cortical screw in syndesmosis fixation.[21] The results of this study seem to support the hypothesis that 2 tricortical screws provide sufficient strength of fixation.

Leaving screws in place only to remove them in the case of migration or local irritation means fewer surgical procedures and thus less risk of secondary complications. In this study, removal due to spontaneous loosening and migration was necessary in 2 patients only (6%). As the participating patients routinely were offered complete implant removal at the 1-year follow-up, further problems with spontaneous screw loosening were not seen. Fixation of the syndesmosis with biodegradable screws is still on the experimental stages and is not widely used. Such fixation is, however, motivated by the same idea as in our study of not having to remove the screws after the syndesmosis has healed. The high incidence of deep surgical site infections in this material (6.3%) was considered coincidental and unrelated to either method of syndesmotic fixation.

The indications for syndesmotic transfixation in this study are well in line with general recommendations, even though the issue is controversial.[22,23] Even though the incidence of syndesmosis transfixation was high in this study, even higher incidences have been reported. Takao et al found a 87% incidence of syndesmotic ruptures in 38 B-type ankle fractures diagnosed by arthroscopy.[24] In comparison, Ebraheim et al reported a 72% incidence of the use of syndesmosis screws in 32 cases of C-type ankle fractures.[25]

The Olerud Molander functional outcome score is reported to correlate with quality of life and the presence and degree of displacement, osteoarthritis, patient satisfaction, as well as dorsiflexion of the ankle.[14,15] The improved mean functional score (16.1%) and reduction in pain (18.2%) at 3 months in the test group was, in our opinion, clinically relevant. The difference in the functional scores after 1 year

TABLE 5. Complications and Events Within the First Postoperative Year

	Quadricortical Group (n = 30)	Tricortical Group (n = 34)	Difference
Loss of reduction of the syndesmosis after 1 yr	5	1	NS
Revision due to deep infection	3	1	NS
Revision due to malreduction of the syndesmosis	1	1	NS
Superficial infection	2	0	NS
Tricortical syndesmosis screws too long	—	1	—
Postoperative drop foot	0	1	NS
Reduction of joint space less than 50% after 1 yr	5	4	NS
Fracture of tricortical screws at 1 yr	—	5 (in 3 pts)	—
Removal of tricortical screws during the first yr	—	3 (in 2 pts)	—
Routine removal of all implants within the first yr	3	3	NS

NS, not significant; —, data not available.

(6.6%) was neither statistically significant nor clinically relevant.

Loaded dorsiflexion in the uninjured ankles in this material (41.5°) was higher than Lindsjö et al found using the same method[13] and what Michelson and Waldman found in a loaded cadaver model,[19] 32.5° and 34°, respectively. The measurements were performed in the same manner by the primary author. Average measure ICC of the uninjured ankles was 0.8773 (CI 0.7875–0.9292), demonstrating adequate consistency of the measurements.

The functional score was significantly higher in the tricortical group compared with the controls at 3 months, the most apparent differences found being pain ($\Delta = 4.2$), stiffness ($\Delta = 1.3$), the ability to walk stairs ($\Delta = 1.0$), and running ($\Delta = 1.0$). All these parameters may be related to the dynamics of the distal tibiofibular syndesmosis. These differences were probably contributed by the fact that the patients in the tricortical group were allowed full weight bearing slightly sooner (8 weeks), whereas the patients in the quadricortical group had their syndesmosis rigidly fixed until removal of their syndesmosis screws postoperatively (9.4 weeks). It may thus be assumed that tricortical screw fixation were beneficial for these parameters of early function. The improved dorsiflexion found in the tricortical group ($\Delta = 2.8°$) further support this theory, in spite the difference not being statistically significant ($P = 0.297$).

The fact that the functional score was still higher in the tricortical group after 1 year indicates that quadricortical fixation of an injured syndesmosis brings on long-term reduction in function, possibly due to increased perisyndesmotic scarring and prolonged immobilization of the distal tibiofibular joint. However, as dorsiflexion was just slightly lower in the quadricortical group ($\Delta = 2.8°$), the decreased functional scores found in the quadricortical group cannot be explained by joint stiffness alone. A certain error of measurement may also be expected and a difference of less than 3° has little clinical significance.

Even though differences in the functional results between the groups may be influenced by the mixture of fracture types, the selection of patients to either group was entirely at random. Furthermore, the fracture types in Table 1 were comparable within the groups.

The fact that there were more late displacements in the quadricortical group (3 vs. 1) may be due to the removal of the syndesmosis screws after just 2 to 3 months. In the case of premature removal of the syndesmosis screw, instability and secondary displacement may occur. On the other hand, a type of fixation that does not need removal may provide stability of the syndesmosis until complete healing unless the screws loosen prematurely. The results of this study do not indicate that tricortical screws are inferior in terms of holding strength.

This study supports the hypothesis that tricortical screw fixation of a ruptured syndesmosis is adequate and improves early function compared with the traditional transsyndesmotic fixation with bicortical holds in the tibia. However, at 1 year, there were no statistical differences between the 2 groups in functional score, pain, and dorsiflexion.

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