Functional outcome of routine versus on-demand removal of the syndesmotic screw

a four-year follow-up

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Aims

The primary aim of this study was to present the mid-term follow-up of a multicentre randomized controlled trial (RCT) which compared the functional outcome following routine removal (RR) to the outcome following on-demand removal (ODR) of the syndesmotic screw (SS).

Methods

All patients included in the 'ROutine vs on DEmand removal Of the syndesmotic screw' (RODEO) trial received the Olerud-Molander Ankle Score (OMAS), American Orthopaedic Foot and Ankle Hindfoot Score (AOFAS), Foot and Ankle Outcome Score (FAOS), and EuroQol five-dimension questionnaire (EQ-5D). Out of the 152 patients, 109 (71.7%) completed the mid-term follow-up questionnaire and were included in this study (53 treated with RR and 56 with ODR). Median follow-up was 50 months (interquartile range 43.0 to 56.0) since the initial surgical treatment of the acute syndesmotic injury. The primary outcome of this study consisted of the OMAS scores of the two groups.

Results

The median OMAS score was 85.0 for patients treated with RR, and 90.0 for patients treated with ODR ($p = 0.384$), indicating no significant difference between ODR and RR. The secondary outcome measures included the AOFAS (88.0 in the RR group and 90.0 for ODR; $p = 0.722$), FAOS (87.5 in the RR group and 92.9 for ODR; $p = 0.399$), and EQ-5D (0.87 in the RR group and 0.96 for ODR; $p = 0.092$).

Conclusion

This study demonstrated no functional difference comparing ODR to RR in syndesmotic injuries at a four year follow-up period, which supports the results of the primary RODEO trial. ODR should be the standard practice after syndesmotic screw fixation.

Take home message

- This study demonstrated no functional difference comparing on demand removal to routine removal in syndesmotic injuries at a four year follow-up period, which supports the results of the primary RODEO trial.
- On-demand removal should be the standard practice after syndesmotic screw fixation.

Introduction

In 15% to 20% of all surgically treated ankle fractures, a syndesmotic injury is present.[1,2] The syndesmotic screw (SS) is still most commonly used of all surgical options.[3] Until

recently, the SS was routinely removed after eight to 12 weeks, and in some studies even between six and eight weeks, as screws were thought to restrain ankle function and cause pain.[3-5] Breaking of syndesmotic screws at an intraosseous level is held responsible for pain and impaired function.[6] Recently, the 'ROutine vs on DEmand removal Of the syndesmotic screw' (RODEO) trial, a multicentre randomized controlled trial (RCT), was published.[7] This trial studied functional outcome following placement of the SS in unstable ankle fractures and subsequent routine or on demand removal. Patients filled in the Olerud-Molander Ankle Score (OMAS),[8] American Orthopaedic Foot and Ankle Hindfoot Score (AOFAS),[9] and visual analogue scale (VAS) to score pain. The active range of motion was tested and scored in number of degrees in flexion and extension. The primary outcome was functional outcome at 12 months following syndesmotic fixation and subsequent routine or on demand removal. Additionally the functional outcome was also scored at three and six months.[7] This trial showed non-inferior functional outcome of on-demand removal (ODR; median OMAS 80; interquartile range (IQR) 65 to 100) compared to routine removal (RR; median OMAS 85; IQR 60 to 95).[7] Other studies have shown that functional improvement is known to continuously improve after more than 12 months following syndesmotic fixation.[10,11] However, these studies with longer follow-up did not compare the outcome following RR to the outcome following ODR. Therefore, our primary aim was to compare the functional outcome following RR to the outcome following ODR of the SS, after a period of four years.[12] We expected results of ODR to be non-inferior, even at longer follow-up, as the screw would be removed when complaints are expected to be hardware-related. Second, the percentage of SS removal following the initial follow-up period are studied. Third, improvement of functional outcome over time is reviewed.

Methods

This study contains a mid-term follow-up of patients previously recruited in the RODEO trial.[7] The initial trial compared functional outcome of RR versus ODR of the SS following syndesmotic injury and was undertaken between 2017 and 2019. The original trial protocol was published and registered at ClinicalTrials.gov (NCT02896998).[13] In total, 152 patients were randomized to receive RR or ODR (73 patients received RR and 79 patients received ODR). Mean age was 45.3 years (standard deviation (SD) 15) in the RR group and 48.3 years (SD 14) in the ODR group.

All included patients in this trial had traumatic syndesmotic injury, surgically treated within two weeks using one or two syndesmotic screws. Both unstable ankle fractures with syndesmotic disruption and isolated syndesmotic injuries were included. Exclusion criteria were: Injury Severity Score (ISS)[14] > 15; insufficient physical condition to allow screw removal; concomitant injury of the ipsi- or contralateral side or other medical conditions hampering rehabilitation; and insufficient comprehension of English or Dutch language. Randomization was performed centrally (1:1 using variable blocks of four, six, and eight, stratified per institute and age category) by the coordinating investigator (FS), who then notified the patient and treating (orthopaedic) surgeon (RvV, NS, BvD, TS, JH, EF, JH, NS, JW).

In the RODEO trial, patients randomized for RR were scheduled for SS removal routinely at eight to 12 weeks after syndesmotic fixation according to protocol. If the screws were already broken at that time, surgeons were advised to proceed with removal when the screws were thought to cause complaints. The definition of ODR was 'retaining the screw unless there were complaints warranting removal' (e.g. localized pain, screw backing out causing skin irritation, infection). Patients (or surgeon) could opt for removal at any time, but were usually advised to wait, at least until fracture healing allowed for any additional implants to be removed (if necessary), in order to combine these procedures in case of clinically relevant hardware complaints.[7] Exact timing of removal and postoperative treatment was left to the discretion of the treating physician. At three, six and twelve months post-surgery, range of motion and functional outcome questionnaires were filled in.

In the ODR group, of the 79 patients, 61 retained their screw (77.2%). Of the retained screws, 19 were broken (31.1%). Additionally, of the 18 patients who underwent screw removal, the screw was found to be broken in ten cases (55.6%).

Mid-term follow-up

Dutch patients who were included in the RODEO trial were asked for permission to be contacted for additional follow-up when signing the informed consent form. Patients who gave permission were contacted by telephone and asked to provide written informed consent to participate in the current study.

Patients were asked to fill in a questionnaire about the function of the surgically treated ankle and quality of life. The questionnaire consisted of the OMAS, AOFAS, Foot and Ankle Outcome Score (FAOS),[15] EuroQol five-dimension questionnaire (EQ-5D),[16] and additional questions regarding further surgery at the initial 12-month follow-up. The questionnaires are shown in the Supplementary material.

The primary outcome measurement was the OMAS. This is a patient-reported outcome measure (PROM), developed for patients with ankle fractures, with a final score of 0 to 100. A score of 0 indicates totally impaired function and 100 indicates full function.[8] At 12 months of follow-up, the OMAS has a minimal clinical important difference (MCID) ranging from 7.5 to 10.5 and a minimal detectable change (MDC) of 4.7.[17]

The AOFAS is a PROM that includes nine items and can be divided into three subscales (pain, function and alignment).[9] The AOFAS accumulates to a total score ranging from 0 points (indicating severe pain and impairment) to 100 points (no symptoms or impairment). The MCID of the AOFAS has previously been calculated to be between 7.9 to 30.2 in hallux valgus surgery and 30 points for patients with septic ankle arthritis.[18,19]

FAOS is a self-administered PROM and consists of 42 items divided into five subscales: pain (nine items), other symptoms (seven items), function in daily living (ADL) (17 items), function in sport and recreation and foot (four items), and ankle-related quality of life (five items). Raw scores are transformed to a scale from 0 (extreme symptoms) to 100 (no symptoms). The MCID of the FAOS has been calculated for the separate domains of the FAOS, but not for the overall score.[20,21]

The EQ-5D is a self-administered PROM, which measures health status with five levels of severity on five

Table I. Baseline patient and surgical characteristics.

Variable	RR (n = 53)	ODR (n = 56)
Male, n (%)	35 (66.0)	33 (58.9)
Mean age, yrs (SD)	46.7 (13.4)	47.3 (13.4)
Age, yrs, n (%)		
< 60	40 (75.5)	47 (83.9)
≥ 60	13 (24.5)	9 (16.1)
Mean weight, kg (SD)	88.6 (15.8)	89.6 (17.9)
Mean BMI, kg/m2 (SD)	29.0 (5.4)	28.4 (5.3)
Nicotine use, n (%)	8 (15.1)	12 (21.4)
Alcohol abuse, n (%)	5 (9.4)	7 (12.5)
Substance abuse, n (%)	4 (7.5)	1 (1.8)
Missing, n	6 (11.3)	4 (7.2)
Diabetes mellitus, n (%)		
Type 1	0	0
Type 2	2 (3.8)	1 (1.8)
COPD, n (%)	1 (1.9)	2 (3.6)
PAD, n (%)	0	0
Injury, n (%)		
Weber B	7 (13.2)	5 (8.9)
Weber C	26 (49.1)	27 (48.2)
Maisonneuve	9 (17.0)	14 (25.0)
Isolated syndesmosis	0 (0.0)	1 (1.8)
Other	9 (17.0)	9 (16.1)
Missing	2 (3.8)	
ASA classification, n (%)		
I	26 (49.1)	21 (37.5)
II	20 (37.7)	29 (51.8)
III	2 (3.8)	2 (3.6)
Missing	5 (9.4)	4 (7.2)
Mean surgery duration, mins (SD)	61.0 (29.6)	61.0 (31.1)
Tourniquet use, n (%)	15 (28.3)	11 (19.6)
Missing, n (%)	17 (32.1)	15 (26.8)
Screws, n (%)		
1	37 (69.8)	35 (62.5)
2	15 (28.3)	21 (37.5)
Screw diameter, mm, n (%)		
2.7	1 (1.9)	1 (1.8)
3	2 (3.8)	0 (0.0)
3.5	45 (84.9)	53 (94.6)
4	2 (3.8)	1 (1.8)
4.5	2 (3.8)	1 (1.8)
Missing	1 (1.9)	0 (0.0)
Cortices, n (%)		
3	41 (77.4)	49 (87.5)
4	11 (20.8)	7 (12.5)
Missing	1 (1.9)	0 (0.0)
Mean level, mm (SD)*	23.7 (7.2)	25.7 (10.9)
Missing, n (%)	2 (3.8)	3 (5.4)
Mean time in cast after surgery, wks (SD)	5.12 (1.7)	4.9 (1.9)
Missing, n (%)	5 (9.4)	5 (8.9)
Complication of fixation, n (%)	11 (20.8)	9 (16.1)
Missing, n (%)	1 (1.9)	0 (0.0)
Mean wks to full weightbearing (SD)	5.1 (2.2)	5.2 (2.1)
Missing, n (%)	2 (3.8)	1 (1.8)

*Measured from tibial plafond to most distal syndesmotic screw.
ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; ODR, on-demand removal; PAF, peripheral artery disease; RR, routine removal; SD, standard deviation.

different domains:[16,22] mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It also includes scale from 0 to 100 from which patients to select a number, which correlates the best with their health at that specific day.

We used Castor Electronic Data Capture to digitally send and receive the questionnaires.[23]

Statistical analysis

Continuous data were compared using the Mann-Whitney U test if data were unrelated, and Wilcoxon signed-rank test if data were related. Nominal variables were compared using the Fisher's exact test. We tested for normality using the Kolmogorov-Smirnov test. The medians of non-normal data were compared using independent samples and the means of normal data were compared using the Mann-Whitney U test.

All analyses were performed using statistical software package SPSS 20.0 (IBM, USA), and statistical significance was set at a p-value < 0.05.

Results

Out of 152 patients in the RODEO trial, 109 ((71.7%; RR n = 53, ODR n = 56) returned the questionnaire. Median follow-up was 50 months since surgical treatment of traumatic syndesmotic injury (IQR 43.0 to 56.0). Baseline characteristics are shown in Table I.

In total, 24 out of 56 patients (42.9%) in the ODR group had SS removal after 49 months. The first removal in the ODR group was 21 weeks following fixation. Seven patients had the SS removed because of pain, two patients complained of stiffness, three patients because of a broken or loosened screw, three patients because they wanted the material removed without further explanation, and nine patients had removal of the SS because of a combination of the aforementioned reasons.

In the RR group, 16 patients (30.2%) had all implants removed. In the ODR group, removal of all implants was performed in nine patients (16.1%). In the RR group, eight screws were broken (15.1%). Median OMAS scores were 72.5 (IQR 58.75 to 100) among these patients, and 85.0 (IQR 75.0 to 100) among patients in the RR group with an intact SS.

In the ODR group, 22 screws were found to be broken (39.3%). Median OMAS score was 90.0 (IQR 72.5 to 95.0), and 90.0 (IQR 80.0 to 100) for patients in the ODR group with an intact SS. In the ODR group, median removal time among patients of who the SS was removed was 31.5 weeks when the screw was broken and 47.0 when the screw was intact.

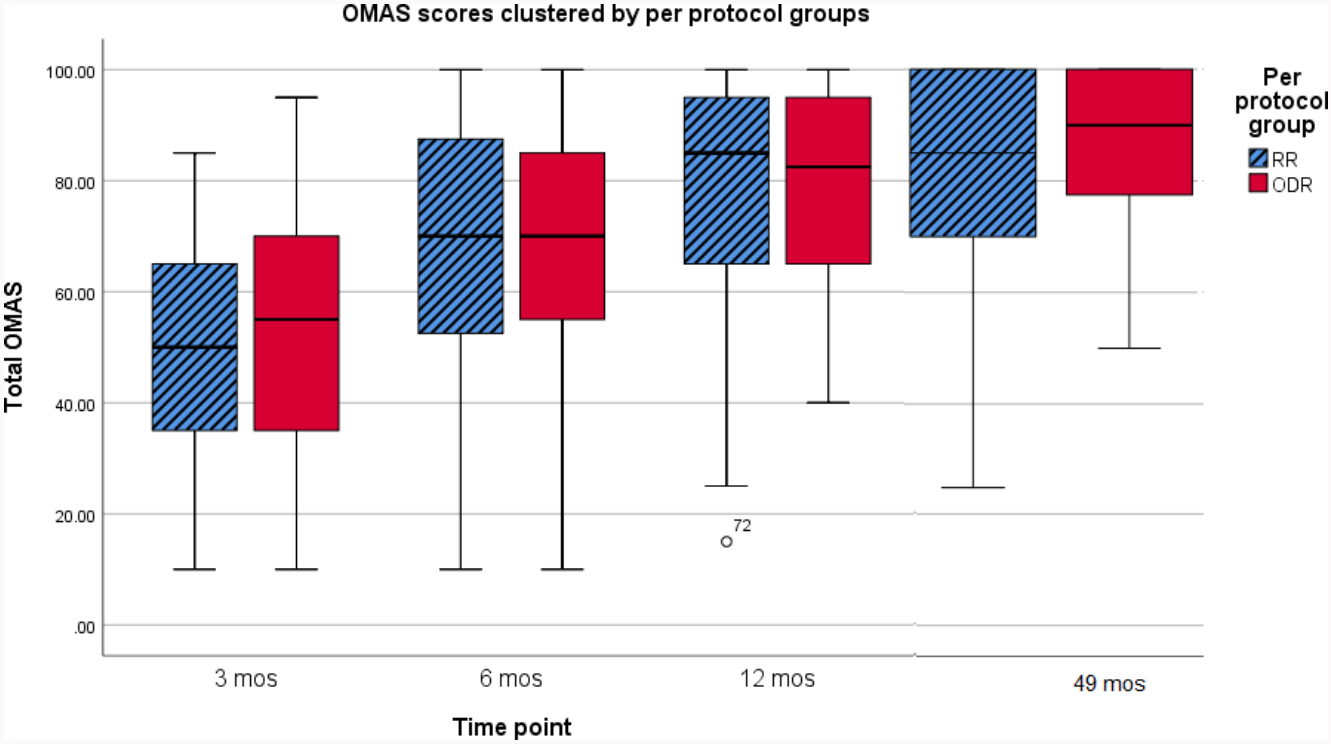

Fig. 1
Olerud-Molander Ankle Scores clustered by per protocol groups.

Median OMAS scores are shown in Figure 1. These were 85.0 (IQR 70 to 100) for patients treated with RR and 90.0 (IQR 76.25 to 100) for patients treated with ODR (p = 0.384, Mann-Whitney U Test).

Secondary outcomes

AOFAS

The median AOFAS score for patients following RR was 88.0 (IQR 81 to 100) and 90.0 (IQR 79.5 to 100) following ODR (p = 0.722, Mann-Whitney U Test).

FAOS

Two patients did not complete the FAOS (1.8%), one patient following RR and one patient following ODR. The median of the total FAOS score was 87.5 (IQR 72.2 to 98.7) in the RR group and 92.9 (IQR 82.7 to 98.8) in the ODR group (p = 0.399, Mann-Whitney U Test). The FAOS scores are shown in Table II.

EQ-5D

The median index value for patients following RR was 0.87 (IQR 0.78 to 1.00) and for patients following ODR, the median index value was 0.96 (IQR 0.81 to 1.00) (p = 0.092, Mann-Whitney U Test).

Table II. Foot and Ankle Outcome Scores.

Subscales, median (IQR)	RR	ODR	p-value*
Symptoms	85.7 (67.9 to 100)	85.7 (67.9 to 96.4)	0.917
Pain	91.7 (73.6 to 100)	97.2 (88.9 to 100)	0.289
Function in daily living	96.3 (83.8 to 100)	98.5 (92.6 to 100)	0.327
Function in sports and recreational activities	85.0 (60.0 to 100)	85.0 (60.0 to 100)	0.642
Quality of life	75.0 (62.5 to 100)	81.3 (62.5 to 100)	0.369

*Mann-Whitney U test.
IQR, interquartile range; ODR, on-demand removal; RR, routine removal.

Discussion

The current study demonstrates no difference in functional outcome comparing ODR to RR of syndesmotic screws in syndesmotic injuries at a mean follow-up period of four years. The primary outcome of this study consisted of the OMAS, which was 85.0 for patients treated with RR and 90.0 for patients treated with ODR (p = 0.384), indicating no significant difference between ODR and RR. Furthermore, this difference does not reach the MCID.[17] This is in line with the observations in our initial study, which showed that there were no significant differences at a 12-month follow-up. Furthermore, these results are comparable with outcomes from recent review studies indicating that there is no evidence to support the routine removal of syndesmotic screws.[24,25]

In addition, there was no difference in AOFAS, FAOS, and EQ-5D between ODR and RR which is also in line with our initial study.

In previous years, a wide range of PROMs have been used in orthopaedic foot and ankle literature. Unfortunately, there is no consensus on which one is more accurate in measuring treatment effects after foot and ankle surgery. In this follow-up study, we additionally used the FAOS for subjective functional outcome. Sierevelt et al[26] demonstrated in their systematic review, comparing various PROMS, that

FAOS showed promising outcome measures for evaluation of patients with foot and ankle conditions. Others indicated that the FAOS is a reliable and valid questionnaire to assess symptoms and functional limitations of the foot and ankle.[27–29] In this study, the median of the total FAOS score was 87.5 in the RR group and 92.9 in the ODR group (p = 0.399), indicating no significant difference.

Furthermore, this study showed that only 6/56 patients (10.7%) in the ODR group had removal of the SS in the follow-up period between 12 and 50 months. This leads to a total removal rate of 42.9% following ODR. The removal rate in the current study (after four years) was expected to be higher, but this included mainly removal of all implants in one single procedure instead of two.[30] This shows that more than half of the patients have no need for a separate SS removal procedure, compared to RR. This has advantageous economic consequences and avoids possible complications following removal.[31] The literature is replete with the dilemma of routine syndesmotic screw removal and possible complications that follow. Some authors suggest that removing the syndesmotic screw is necessary for anatomical restoration and therefore creating more range of motion.[5,32] On the other hand, a more recent study showed that screw removal does not significantly influence the radiological outcomes of rotational ankle fractures.[33] Also, Boyle et al[34] found no significant functional, clinical, or radiological benefits in 51 patients who underwent randomization between surgical removal and retention of the syndesmotic screw. Additionally, the rate of surgical site infections following removal of the SS is relatively high. [34–37]

A broken syndesmotic screw has always been topic of debate. In this study, the OMAS of patients in the ODR with a broken SS were equal to these in the ODR group with an intact SS. This suggests that a broken screw is not necessarily a reason for removal, as previously reported in the literature.[38] The lower OMAS in patients with a broken screw in the RR group suggests that management should be reconsidered when screws break early (i.e. consider on demand removal).

This study had several limitations. First, follow-up was carried out by an online questionnaire. Therefore, we were not able to make any definite statement regarding the range of motion (ROM). However, in the RODEO trial, there were no significant differences considering ROM at any time point and differences with the healthy side were already small after 12 months. Furthermore, functionality does also partially include ROM, although not scored in degrees. Following ankle fracture surgery, there is less improvement in functionality at a mid-term follow-up. Therefore, we consider the additional value of midterm ROM lower than measurements after 12 months.[39] We believe that the current study can make an accurate estimate of satisfaction considering the ROM and/or function from a patient perspective. Second, the lack of radiological imaging at time of follow-up might be considered another limitation of this study. As a result, this could lead to a missing population of patients with broken screws that have not yet led to symptoms. However, the benefit of radiological imaging in functional outcomes can be questioned, considering these do not necessarily correlate with the patient subjective reported outcomes.[38,40] Third, as described in the initial RODEO study, patients were treated in various hospitals, leading to a heterogeneity in postoperative treatment at one-year follow-up. And finally, although our follow-up cohort has a relatively high response-rate, this is not a completely identical cohort. Therefore, this study may have been confounded by response bias.

Screw fixation remains a frequently used technique for syndesmotic injury repair. There is, however, no consensus supporting retaining nor removing the syndesmotic screw in the current literature. This study showed that ODR remains non-inferior to RR in multiple PROMs at a median follow-up of four years. Therefore, this study reinforces the results of the RODEO trial (ODR of syndesmotic screws is non-inferior to RR). Therefore, we suggest that ODR should be standard practice after syndesmotic screw fixation.

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Data sharing

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Ethical review statement

The RODEO trial (NL58539.018.16) was approved on 6 September 2016 by the Medical Ethical Review Committee (METC) of the Academic Medical Centre, with local reference number "2016_197". Patients who signed permission to be contacted for additional studies were contacted.

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