Implant removal after internal fixation of a femoral neck fracture: effects on physical functioning

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Conflict of interests and source of funding

Members of the research team received a grant from Fonds NutsOhra (grant number T-0602-43), The Netherlands Organization for Health Research and Development (ZonMw; grant number 171102008), Physicians' Services Incorporated Foundation (grant number 08-18), and Canadian Institutes of Health Research (grant number 177466). The funding agencies were not involved in the study design, data collection, data analysis, manuscript preparations or publication decisions for this manuscript.

Abstract

Objectives: The effect of implant removal after internal fixation of a femoral neck fracture on physical functioning was analyzed. Characteristics of patients who had their implant removed were studied, as it is currently unknown in which type of patients implants are removed and what effect removal has on function.

Design: Secondary cohort study alongside a RCT.

Setting: Multicenter study in 14 hospitals.

Patients and Intervention: Patients who had their implant removed after internal fixation of a femoral neck fracture are compared with patients who did not.

Main outcome measurements: Patient characteristics and quality of life (Short Form-12 (SF-12), Western Ontario McMaster Osteoarthritis Index (WOMAC)) were compared. Matched pairs were selected based on patient/fracture characteristics and pre-fracture physical functioning.

Results: Of 162 patients, 37 had their implant removed (23%). These patients were younger (median age 67 versus 72 years, P=0.024) and more often independently ambulatory pre-fracture (100% versus 84%, P=0.008) than patients who did not. They more often had evident implant back-out on X-rays (54% versus 34%, P=0.035), possibly related to a higher rate of Pauwels 3 fractures (41% versus 22%, P=0.032). In time, quality of life improved more in implant-removal patients (+2 versus -4 points SF-12 (physical component), P=0.024; +9 versus 0 points WOMAC, P=0.019).

Conclusions: Implant removal after internal fixation of a femoral neck fracture positively influenced quality of life. Implant-removal patients were younger and more often independently ambulatory pre-fracture, more often had a Pauwels 3 fracture, and an evident

implant back-out. Implant removal should be considered liberally for these patients if pain persists or functional recovery is unsatisfactory.

Level of evidence: II

Keywords: Femoral neck fracture, hip fracture, internal fixation, implant removal, patient functioning.

Introduction

Internal fixation of femoral neck fractures can sometimes result in long-term physical limitations and pain, even if fractures have healed uneventfully.[1] These limitations can be caused by physical changes such as tissue damage, scarring, and loss of muscle strength due to the injury and surgical exposure, or femoral neck shortening due to impaction at the fracture site.[1] The implant can cause local irritation and functional impairment.[2-4] In some patients with persistent complaints the implant is therefore removed after fracture healing. The rate of implant removal after internal fixation of femoral neck fractures is unknown. Reported implant removal rates after internal fixation of fractures at various anatomical locations including the hip, ranges from 16% to 81%.[5,6]

Guidelines on when to remove implants do not exist, mainly due to a lack of evidence. Several surveys among surgeons have indicated that patient related factors (*e.g.*, local irritation, pain, (unexplained) complaints, or patients request), possible carcinogenic/toxic, or unknown systemic effects, and expected problems with later removal due to bony overgrowth are considered reasons for implant removal.[2-4,7] A greater risk of future fractures due to stress shielding may also be a reason.[8,2,4] General reasons not to remove implants could be the risk of tissue or nerve damage, or an adverse event (mainly wound infection or hematoma) associated with secondary surgery. The costs of a second surgery and rehabilitation period may also play a role. Two cohort studies have indicated that removal of implants, at various anatomical locations, improves pain relief and function.[9,10] In other studies, however, the relief of complaints was not found.[11,2,7]

To the best of our knowledge, implant removal after internal fixation of femoral neck fractures has not been reported in detail. The effect of implant removal on physical functioning in these patients is therefore unknown. It is also unknown which patients are

candidates for removal. Therefore, the aim of this study was to analyze the effect of implant removal after internal fixation of a femoral neck fracture on physical functioning. Characteristics of patients who had their implant removed were also described.

Patients and Methods

Population

This study was a secondary cohort study to the Dutch sample of an international randomized controlled trial, the FAITH trial (Fixation using Alternative Implants for the Treatment of Hip fractures, NCT00761813).[12] The primary objective of the FAITH trial was to assess the impact of internal fixation implants (sliding hip screw versus multiple cancellous screws) on rates of revision surgery at two years in elderly patients with femoral neck fractures (*i.e.,* AO type 31-B fractures).[13] In the Netherlands 14 hospitals participated and randomized 250 patients between February 2008 and August 2009. These patients were adults aged >50 years, who were ambulatory and not cognitively impaired pre-fracture. Patients had either (a) an undisplaced fracture, or (b) a displaced fracture in ASA 1-2 patients, who were 50-80 years old, with a fracture that could be reduced closed.[14] Surgeries were either performed or supervised by an experienced surgeon. All patients were allowed weight bearing as tolerated after surgery.

In the current study, all Dutch FAITH patients who healed after internal fixation were studied. Patients who had their implant removed were compared with patients who did not (control group). Patients who had a revision surgery due to implant failure, non-union, or avascular necrosis (*i.e.,* implant switch or salvage arthroplasty) were excluded. Patients who had a primary arthroplasty due to an unsuccessful fracture reduction were also excluded. The indication for implant removal was persisting pain and/or functional limitation in various degrees, which was considered to be (possibly) caused by the implant. The decision to remove the implant was left to the discretion of the treating surgeon. The implant was removed approximately one year after the fracture surgery if the fracture had healed.

Data and measurements

Patient baseline characteristics, fracture characteristics, and follow-up data, including health-related quality of life (Short Form-12 (SF-12)) and disease-specific quality of life scores (Western Ontario McMaster Osteoarthritis Index (WOMAC)) were available from the FAITH trial.[15,16] In order to calculate the baseline (*i.e.*, pre-fracture) score, patients completed the questionnaires asking for their pre-fracture quality of life within one week after the fracture. SF-12 scores were converted to a norm-based score and compared with the norms for the general population of the United States (1998), as weighing factors for the Dutch population were not available.

X-rays were also collected. In order to study the relation between implant back-out and implant removal, a single investigator scored all X-rays for signs of 'evident implant back-out'. This was defined as back-out with evident increasing distance of the distal end of the implant in relation to the lateral femoral cortex (Figure 1).

Statistical analysis

Analyses were performed using the Statistical Package for the Social Sciences (SPSS, version 16.0, SPSS Inc., Chicago, IL, USA).Baseline and fracture characteristics, as well as SF-12 and WOMAC scores at baseline (*i.e.,* pre-fracture) and after two years follow-up were compared. The change in scores between these two moments was calculated using the formula: Change Score = $\text{Score}_{\text{2 years}} - \text{Score}_{\text{baseline}}$. Continuous data are presented as medians with percentiles, categorical variables as numbers and percentage. In the crude analysis, groups were compared using a Mann Whitney U-test (continuous data) or a Chi-squared test (categorical data).

In order to study the effect of implant removal on patient functioning more specifically, a matched pair analysis was performed. A matched control was searched for all

implant removal patients with complete follow-up data. Controls were considered adequate if they had a comparable age (<5 years difference), identical ASA score (American Society of Anesthesiologists classification), pre-fracture living status, pre-fracture use of ambulatory aids, fracture classification (Garden I/II versus III/IV and Pauwels 1-2 versus Pauwels 3), type of implant, and a comparable WOMAC score at baseline (<5 points difference). Use of a single control for multiple patients was allowed. In the matched pair analysis, SF-12 and WOMAC scores for the implant removal patients were calculated for the follow-up moment immediately before implant removal (mostly 12 or 18 months after initial fracture surgery) and at the first follow up moment after removal (mostly 18 or 24 months after initial fracture surgery). For the matched control the scores at the same follow-up moment in time were used. The change in scores between these two moments was calculated using the formula: Change Score = $\text{Score}_{\text{after removal}} - \text{Score}_{\text{before removal}}$. Groups were compared using a Wilcoxon signed rank test (continuous data). Results with $P<0.05$ (two-sided test) were regarded statistically significant.

Results

Patient, fracture, and treatment characteristics

Of the initial 250 patients, 162 patients healed uneventfully after internal fixation and were included. The remaining 88 patients were excluded, mainly since they had an arthroplasty as salvage procedure (N=69) or during primary surgery (N=16; Figure 2).

Patient, fracture, and treatment characteristics are shown in Table 1. Of the 162 patients who healed after internal fixation 37 patients had their implant removed (23%), at a median of 15 months after initial fracture surgery. Eight patients had an implant removal associated adverse event (22%); four patients sustained a bleeding or hematoma (11%), two patients a trochanteric bursitis (5%), one patient a urinary retention (3%), and one patient a wound infection (3%).

Patients who had their implant removed were significantly younger than patients who did not (median age 67 versus 72 years, P=0.024) and significantly more often independent ambulatory pre-fracture (100% versus 84% independently ambulatory, P=0.008). The implant removal patients also significantly more often had a Pauwels 3 type fracture (41% versus 22%, P=0.031) and an evident implant back-out on X-rays (54% versus 34%, P=0.035).

Crude analysis of patient self-reported health-related and disease-specific quality of life (SF-12 and WOMAC)

At baseline (*i.e.,* pre-fracture) patients who had their implant removed had significantly higher SF-12 scores than patients who healed without implant removal (107 versus 102 points, P=0.038). Especially the physical component summary scores were higher

(Supplemental Table 1). WOMAC scores were not significantly different at baseline (97 versus 95 points, P=0.101).

After two years the SF-12 and WOMAC scores had decreased in patients who had their implant removed as well as in the patients who did not (Table 2). Again, this was mostly apparent in the physical component and function scores (Table 2). However, there was no significant difference in change between the groups; median change in SF-12 score -3 versus -3 points (P=0.700) and WOMAC score -3 versus -4 points (P=0.427; Table 2).

Matched pair analysis

Of the 37 implant removal patients, five patients could not be included in the matched pair analysis because they did not have complete follow-up data. A match could be found for 22 of the remaining patients (Figure 2). The matched pairs had similar characteristics, as expected (Table 1). The only difference was a higher percentage of patients with evident implant back-out in the implant removal group (50% versus 9%, P=0.004).

At the follow-up moment directly before the implant removal (*i.e.*, mostly 12 or 18 months after initial fracture surgery), the implant removal patients reported significantly lower physical functioning scores than the patients who had their implant retained. This is reflected in the SF-12 physical component summary score (44 versus 53 points, P=0.005) and all WOMAC sub-scores (pain 83 versus 100 points, P=0.001; stiffness 75 versus 100 points, P=0.010; function 82 versus 98 points, P=0.002; Table 3). At the follow-up moment directly after the implant removal (*i.e.*, mostly 18 or 24 months after initial fracture surgery), only a significantly lower WOMAC pain sub-score in the implant removal group remained (90 versus 98 points, P=0.036). Despite the second surgery and rehabilitation period, the implant removal patients still had an improvement of their physical functioning scores in the period of their implant removal, whereas the control group had not. This is reflected in an improvement

in SF-12 physical component summary score (2 versus -4 points, P=0.024), WOMAC function sub-score (10 versus 0 points, P=0.030) and WOMAC total score (9 versus 0 points, P=0.019; Table 3).

Discussion

Implant removal after internal fixation of a femoral neck fracture had a significantly positive effect on patient functioning. The functional outcome scores of both the SF-12 and the WOMAC improved significantly more in the patients who had their implant removed than in the patients who did not, in a similar time period. Even though the implant removal patients were significantly more impaired than the control group before implant removal, they had similar general health-related and disease-specific quality of life after two years follow-up, which could be related to the implant removal. This positive effect of implant removal is confirmed in other studies on implant removal for different fractures.[9,10] The positive effect of implant removal may in fact even have been underestimated, as quality of life measurements were sometimes performed shortly after the implant removal surgery (*i.e.*, <6 months). Patients could therefore still have been rehabilitating from the second surgery at the time of follow-up. This may also explain why the WOMAC pain sub-scores were not significantly different between the groups after implant removal, although P-values approximated the 0.05 significance threshold.

The current study again emphasizes that disease-specific quality of life scores (*e.g.*, WOMAC) seem more appropriate in hip fracture patients than general health-related quality of life scores (*e.g.*, SF-12). The problem in the hip fracture population is a complex assortment of issues ranging from baseline health and frailty, social isolation and support, mental status and joint function and pain, which are all expressed in general health-related quality of life. The change in physical functioning through time was better expressed in the WOMAC total and sub-scores, than in the SF-12 total and sub-scores (Table 3).

Patients who had their implant removed after internal fixation of a femoral neck fracture were significantly younger and more often independent ambulatory pre-fracture than

patients who did not. They also reported a better pre-fracture general health-related quality of life. This suggests that these patients were probably more mobile and active, and were therefore more impaired by the implant. Generally, it is likely that this patient category strived for a better outcome and performance level, and were less put off by the idea of a second surgery and rehabilitation period. In a previous study on implant removal after femur fractures, age also influenced the likelihood of removal.[6]

As expected, implant back-out was observed more often in patients who had their implant removed. Weight bearing can cause impaction at the fracture site and may result in femoral neck shortening, causing the implant to back-out.[1] The implant is then interfering with the surrounding soft tissues (*i.e.,* abductor muscles and fascia lata). This can result in pain and functional impairment, causing patients to have their implant removed. Apparently, implant back-out does not always cause complaints severe enough to decide on implant removal, as 34% of patients in the control group retained their implant despite an evident implant back-out. In 46% of patients, on the other hand, the implant was removed without signs of an evident implant back-out. Implant back-out is therefore not always the cause of complaints. Implant removal patients more often had a Pauwels 3 type fracture. A previous study already indicated a Pauwels 3 type fracture as risk factor for femoral neck shortening and therefore causing increased implant back-out.[1]

The reason for implant removal was pain and/or functional impairment in all patients. It was therefore expected that SF-12 and WOMAC scores before implant removal were significantly worse in the implant removal patients, as shown in the results.

Implant removal seems a safe procedure with minimal risk. None of the adverse events that occurred were severe or caused permanent disability. The argument of extra costs seems refutable in this population, as a previously published cost analysis of this study group indicated that the implant removal patients were actually less expensive than the patients who

healed without removal (€10,066 versus €17,405 after two years follow-up).[14] However, a selection bias may have played a role.

The main limitation of this study is the relatively low number of patients included, mainly in the matched pair analysis. If the study would be repeated with a higher number of patients and a longer period of follow-up after implant removal, it is likely that the positive effect of implant removal will even be more obvious. However, this is still the first study providing evidence on this topic, and significant effects are seen, even in this relatively small population. It would also be interesting to measure the effect on physical functioning using more objective parameters, such as gait parameters or muscle strength.[1] Unfortunately, our results can only prove a positive effect of implant removal for the patients who were selected in this study based on their symptoms and general condition. These patients were relatively young, healthy and independent pre-fracture. Results should therefore not be generalized.

In conclusion, implant removal after internal fixation of a femoral neck fracture had a significantly positive effect on patient functioning in this study. Patients who had their implant removed were younger , more often independently ambulatory pre-fracture, had a Pauwels 3 type fracture, and an evident implant back-out than patients who did not. Given the positive effects on patient functioning in this study, we suggest that implant removal should be considered more liberally in these patients, if there are persistent complaints of pain or unsatisfactory functional recovery after internal fixation of a femoral neck fracture.

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Figure legends

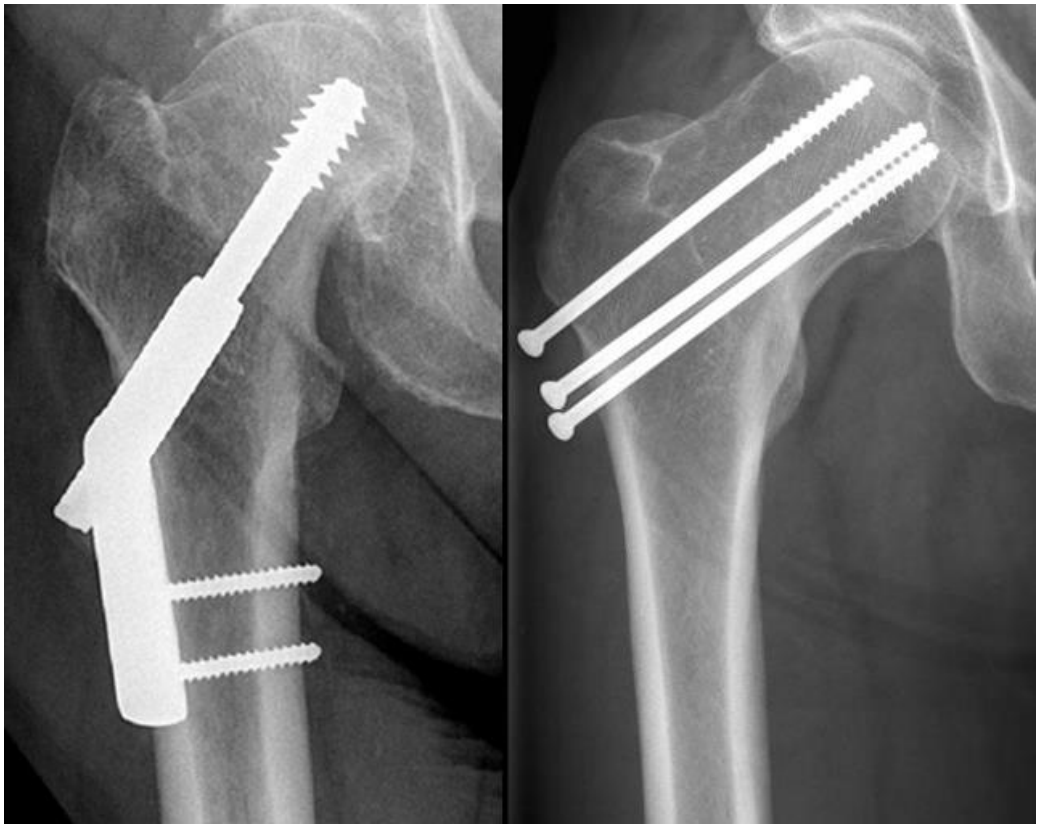

Figure 1. Example of evident implant back-out

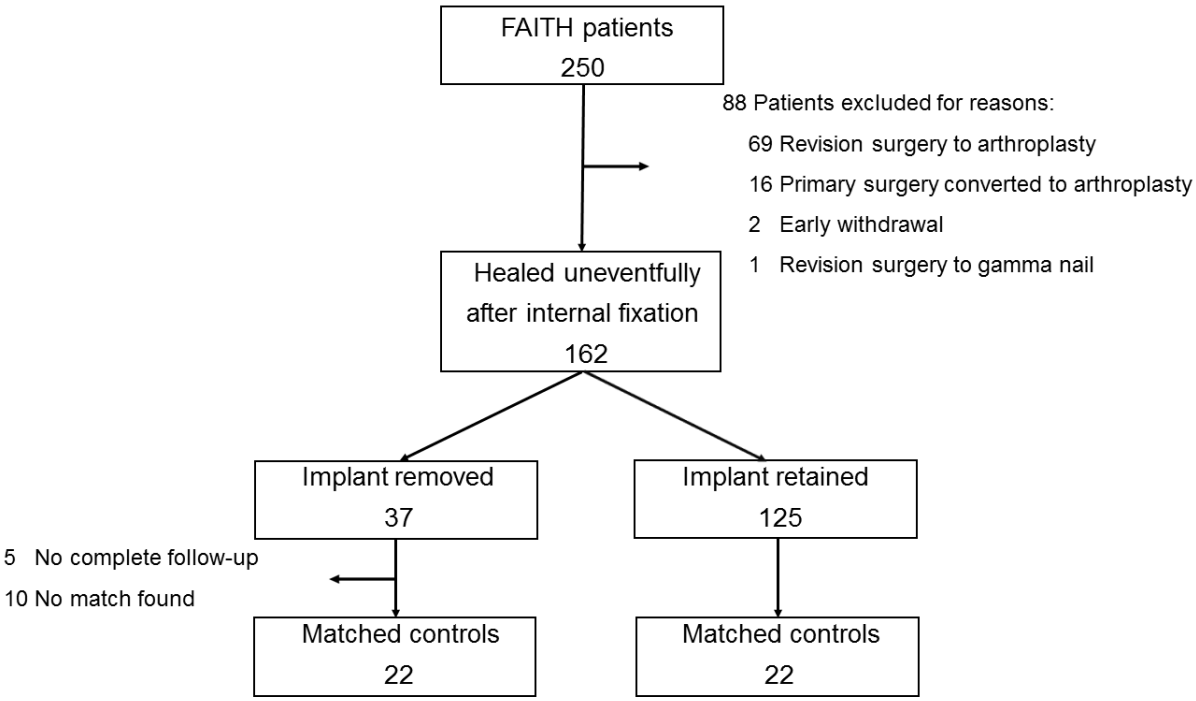

Figure 2. Flowchart of patients participating in this study

Tables

Table 1. Patient characteristics

	Crude analysis			Matched pair analysis		
	Implant removed (N=37)	**Implant retained (N=125)**	**P-value**	**Implant removed (N=22)**	**Implant retained (N=22)**	**P-value**
Age (years) [1*]	67 (60-73)	72 (62-79)	0.024	67 (61-74)	64 (60-72)	0.123
BMI (kg/m²)[1]	24 (21-26)	24 (22-26)	0.522	23 (20-26)	24 (21-28)	0.338
ASA >2[2*]	2 (5)	21 (17)	0.088	0 (0)	0 (0)	1.000
Female[2]	19 (51)	71 (57)	0.577	12 (55)	13 (59)	1.000
Displaced fracture (Garden III-IV)[2*]	18 (49)	38 (30)	0.050	11 (50)	11 (50)	1.000
Pauwels 3 fracture[2*]	15 (41)	27 (22)	0.032	6 (27)	6 (27)	1.000
Pre-fracture institutionalized[2*]	0 (0)	3 (2)	1.000	0 (0)	0 (0)	N.A.
Pre-fracture independent ambulatory[2*]	37 (100)	105 (84)	0.008	22 (100)	22 (100)	N.A.
Evident implant back-out[2]	20 (54)	41 (34)	0.035	11 (50)	2 (9)	0.004
Time to implant removal (months) [1]	15 (13-17)	N.A.	N.A.	15 (13-17)	N.A.	N.A.

BMI, Body Mass Index; ASA, American Society of Anesthesiologists.

Differences between the groups were tested with the Mann Whitney U-test (crude analysis) or Wilcoxon signed rank test (matched pair analysis) for numeric variables, and the Chi-squared test (crude analysis) or McNemar's chi-squared test (matched pair analysis) for categorical variables.

[1] Data are presented as median with P_{25}-P_{75} given between brackets. [2] Data are presented as number with percentages.

[*] This parameter was used to match pairs.

Table 2. Changes in patient self-reported physical functioning after two years follow-up

	Implant removed (N=37)	Implant retained (N=125)	P-value
SF-12			
Change Score 2 years	-3 (-19-4)	-3 (-14-2)	0.700
Change Physical (PCS) 2 years	-6 (-19- -1)	-3 (-13-1)	0.167
Change Mental (MCS) 2 years	3 (-4-9)	1 (-4-6)	0.368
WOMAC			
Change Score 2 years	-3 (-32-0)	-4 (-18-1)	0.427
Change Pain 2 years	-5 (-33-0)	0 (-10-0)	0.156
Change Stiffness 2 years	0 (-38-0)	0 (-25-13)	0.086
Change Function 2 years	-4 (-35-0)	-5 (-19-0)	0.676

SF-12, Short Form 12; WOMAC, Western Ontario McMaster Osteoarthritis Index; PCS, Physical Component Summary; MCS, Mental Component Summary.

Scores were measured at baseline (*i.e.,* pre-fracture) and at two years later. These scores are presented in Supplemental table 1. The change in scores between these two moments was calculated using the formula: Change Score = Score $_{2\ years}$ – Score $_{baseline}$.

Data are presented as median with P_{25}-P_{75} given between brackets. Differences between the groups were tested with the Mann Whitney U-test.

Table 3. Effect of implant removal on patient self-reported physical functioning

	Implant removed (N=22)	Implant retained (N=22)	P-value
SF-12			
Score before removal	99 (87-109)	107 (98-110)	0.062
Physical (PCS) before removal	44 (35-49)	53 (46-56)	0.005
Mental (MCS) before removal	57 (48-62)	53 (50-61)	0.910
Score after removal	104 (92-109)	107 (98-109)	0.236
Physical (PCS) after removal	48 (42-51)	49 (43-52)	0.548
Mental (MCS) after removal	56 (48-61)	59 (56-62)	0.050
Change Score	0 (-4-10)	0 (-2-4)	0.485
Change Physical (PCS)	2 (-4-14)	-4 (-7-0)	0.024
Change Mental (MCS)	0 (-6-4)	4 (0-6)	0.168
WOMAC			
Score before removal	82 (62-88)	98 (88-100)	0.001
Pain before removal	83 (69-90)	100 (95-100)	0.001
Stiffness before removal	75 (50-91)	100 (75-100)	0.010
Function before removal	82 (61-88)	98 (89-100)	0.002
Score after removal	90 (74-98)	93 (87-100)	0.106
Pain after removal	90 (69-100)	98 (90-100)	0.036
Stiffness after removal	81 (75-100)	94 (88-100)	0.057
Function after removal	91 (71-100)	95 (85-100)	0.145
Change Score	9 (-2-16)	0 (-7-2)	0.019
Change Pain	5 (-1-11)	0 (-1-1)	0.051
Change Stiffness	6 (-3-38)	0 (-13-3)	0.176

Change Function	10 (-2-18)	0 (-6-3)	0.030

SF-12, Short Form 12; WOMAC, Western Ontario McMaster Osteoarthritis Index; PCS, Physical Component Summary; MCS, Mental Component Summary.

Scores were measured at the follow-up moment immediately before implant removal (mostly 12 or 18 months after initial fracture surgery) and after removal (mostly 18 or 24 months after initial fracture surgery). For the matched control the same follow-up moment was used. The change in scores between these two moments was calculated using the formula: Change Score = $\text{Score}_{\text{after removal}} - \text{Score}_{\text{before removal}}$.

Data are presented as median with P_{25}-P_{75} given between brackets. Differences between the groups were tested with the Wilcoxon signed rank test.

Supplemental Table 1. Patient self-reported physical functioning at baseline and after 2 years follow-up

	Total group / Crude analysis			Matched pair analysis		
	Implant removed (N=37)	Implant retained (N=125)	P-value	Implant removed (N=22)	Implant retained (N=22)	P-value
SF-12						
Score baseline	107 (99-114)	102 (92-110)	0.038	109 (100-114)	111 (100-114)	0.958
Physical (PCS) baseline	54 (48-57)	51 (43-55)	0.014	55 (49-58)	54 (51-56)	0.741
Mental (MCS) baseline	54 (48-59)	55 (48-59)	0.997	56 (51-59)	54 (47-61)	0.715
Score 2 years	106 (87-112)	98 (84-108)	0.219	106 (85-111)	107 (97-113)	0.099
Physical (PCS) 2 years	48 (36-52)	44 (33-52)	0.563	47 (37-52)	52 (43-57)	0.046
Mental (MCS) 2 years	58 (47-62)	55 (48-61)	0.296	58 (44-62)	55 (54-62)	0.375
Change Score	-3 (-19-4)	-3 (-14-2)	0.700	-5 (-19-2)	-3 (-12-5)	0.149
Change Physical (PCS)	-6 (-19- -1)	-3 (-13-1)	0.167	-6 (-16- -1)	-2 (-12-2)	0.170
Change Physical (MCS)	3 (-4-9)	1 (-4-6)	0.368	3 (-8-6)	1 (-2-8)	0.274
WOMAC						

Score baseline	97 (93-100)	95 (83-99)	0.101	98 (96-100)	98 (98-100)	0.063
Pain baseline	100 (93-100)	100 (90-100)	0.838	100 (100-100)	100 (100-100)	0.276
Stiffness baseline	100 (88-100)	88 (75-100)	0.091	100 (88-100)	100 (88-100)	0.593
Function baseline	99 (93-100)	95 (81-100)	0.047	99 (96-100)	99 (98-100)	0.157
Score 2 years	91 (65-96)	90 (72-97)	0.889	91 (65-96)	100 (91-100)	0.009
Pain 2 years	95 (65-100)	95 (85-100)	0.189	95 (65-100)	100 (99-100)	0.009
Stiffness 2 years	75 (56-100)	81 (63-100)	0.601	75 (50-100)	100 (88-100)	0.015
Function 2 years	94 (65-98)	90 (67-97)	0.583	94 (65-97)	100 (91-100)	0.024
Change Score	-3 (-32-0)	-4 (-18-1)	0.427	-5 (-35- -2)	0 (-5-2)	0.009
Change Pain	-5 (-33-0)	0 (-10-0)	0.156	-5 (-35-0)	0 (0-0)	0.034
Change Stiffness	0 (-38-0)	0 (-25-13)	0.086	-13 (-38-0)	0 (-13-13)	0.012
Change Function	-4 (-35-0)	-5 (-19-0)	0.676	-6 (-35- -1)	0 (-5-1)	0.023

SF-12, Short Form 12; WOMAC, Western Ontario McMaster Osteoarthritis Index; PCS, Physical Component Score; MCS, Mental Component Score. Scores were measured at baseline (*i.e.*, pre-fracture) and after 2 years follow-up. The change in scores between these two moments was calculated using the formula: Change Score = Score $_{\text{at 2 years}}$ − Score $_{\text{at baseline}}$. Data are presented as median with P_{25}-P_{75} between brackets. Differences between the groups were tested with the Mann Whitney U-test (total group) or Wilcoxon signed rank test (matched pair analysis).