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**Original Article****Title:**

Comparison of a self-administered foot evaluation questionnaire (SAFE-Q) between joint-preserving arthroplasty and resection-replacement arthroplasty in forefoot surgery for patients with rheumatoid arthritis

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44 32 ***This article contains 3 figures and 2 tables.***

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## Abstract

### Objectives

To clarify the difference of patient-based outcome between joint-preserving arthroplasty and resection-replacement arthroplasty in forefoot surgery for patients with rheumatoid arthritis (RA).

### Methods

A total of 63 feet of 49 RA patients who underwent forefoot surgery were asked to answer pre-operative and post-operative self-administered foot evaluation questionnaire (SAFE-Q). Patients were treated with either (1) metatarsal head resection-replacement arthroplasty (28 feet, post-operative mean age 63.8 years, follow-up 4.2 years, DAS28-CRP 2.2) or (2) metatarsophalangeal joint-preserving arthroplasty (35 feet, post-operative mean age 63.1 years, follow-up 3.6 years, DAS28-CRP 2.1) at each surgeon's discretion.

### Results

Mean pre-operative and post-operative subscale scores of SAFE-Q of group (1) and (2) were as follows. Pain and pain-related [(1) pre-op 36.8 to post-op 75.0 vs. (2) pre-op 42.2 to post-op 82.6], physical functioning and daily-living [(1) 43.2 to 68.8 vs. (2) 52.7 to 78.1], social functioning [(1) 44.3 to 72.0 vs. (2) 52.5 to 81.9], general health and well-being [(1) 48.4 to 68.4 vs. (2) 45.5 to 84.4], and shoe-related [(1) 30.1 to 50.3 vs. (2) 30.6 to 64.4]. Both general health and well-being subscale scores ( $P<0.05$ ) and shoe-related subscale scores ( $P<0.05$ ) were significantly more improved in group (2)

compared to group (1).

Conclusions:

Joint-preserving arthroplasty resulted in better patient-based outcomes than resection-replacement arthroplasty.

## Introduction

Rheumatoid arthritis (RA) is frequently associated with forefoot arthritis and painful deformities including hallux valgus (HV), dorsal dislocation of the metatarsophalangeal (MTP) joints, and hammer toe deformity of the lesser toes [1-3]. With recent advances in the pharmacological treatment of RA, such as biologic agents, global forefoot deformities tend to be associated with less erosive changes [4], which has resulted in a trend toward joint-preserving arthroplasty rather than conventional resection arthroplasty of forefoot deformities [5, 6]. However, there is no reliable evidence demonstrating that joint-preservation has an advantage over resection, since fair clinical outcomes of both resection-replacement arthroplasty [7-9] and joint-preserving arthroplasty [5, 10-12] have been reported. In addition, as far as we know, there are no previous reports that assessed these operations' clinical outcomes by a patient-based outcome instrument, which is recently becoming popular in various orthopedic diseases and surgeries [13, 14]. The Japanese Society for Surgery of the Foot (JSSF) has recently developed a patient-based self-administered foot evaluation questionnaire

(SAFE-Q) [15]. The main body of the outcome instrument consists of 34 questionnaire items, which provide five subscale scores (1: Pain and Pain-Related; 2: Physical Functioning and Daily Living; 3: Social Functioning; 4: Shoe-Related; and 5: General Health and Well-Being), and each subscale score ranges from 0 to 100 points. A previous report demonstrated that these subscale scores were all lowest in patients with RA compared to other foot diseases, and the Pain and Pain-Related subscale was more responsive than the SF-36 Bodily Pain subscale [15]. The purpose of this study was to evaluate and compare the mid-term clinical outcomes of both resection-replacement arthroplasty and joint-preserving arthroplasty for forefoot deformities in patients with RA using a patient-based outcome instrument.

## Materials and methods

### Patients and clinical assessment

A total of 63 feet of 49 patients with RA (46 women and 3 men) who underwent forefoot surgery in 3 institutes by 8 senior rheumatoid surgeons from January 2000 to December 2015 were enrolled. Patients were treated with either (1) metatarsal head resection-replacement arthroplasty (mainly Swanson implant replacement of the hallux MTP joint and metatarsal head resection of the lesser toes) [Resection-replacement; 28 feet of 20 patients, post-operative mean age 63.8 years, follow-up 4.2 years (range, 0.5-15 years), Disease activity score assessing 28 joints with CRP (DAS28-CRP) 2.2

(range, 1.1-3.6)] or (2) MTP joint-preserving arthroplasty (mainly modified Scarf osteotomy of the hallux and off-set shortening osteotomy of the lesser toes). [Preserving; 35 feet of 29 patients, post-operative mean age 63.1 years, follow-up 3.6 years (range, 0.5-15 years), DAS28-CRP 2.1 (range, 1.5-2.8)] at the discretion of each surgeon. Patients were radiographically evaluated and asked to answer the pre-operative and post-operative SAFE-Q, and the clinical characteristics of each group when asked to answer post-operative SAFE-Q are shown in Table 1. For the pre-operative SAFE-Q, 53.6% (15/28) of the resection-replacement group and 40.0% (14/35) of the preserving group were administered the questionnaire retrospectively, since the SAFE-Q was published on January 9, 2013. The questions about sports activity (Q35-43) were not included this study. The hallux valgus angle (HVA), first metatarsal and second metatarsal (M1M2) angle, first metatarsal and fifth metatarsal (M1M5) angle, and the recurrence of lesser toe MTP joint subluxation or dislocation were defined by anteroposterior weight-bearing radiographs which were performed pre-operatively and post-operatively when SAFE-Q was administered, as previously described [7]. Briefly, if the axis of the proximal phalanx was displaced by one diaphyseal width or less, it was defined as subluxated, and if it was displaced more than one diaphyseal width, it was defined as dislocated.

This study was conducted in accordance with the ethical standards of the Declaration of Helsinki, and was approved by the Institutional Ethical Review Board at each center (approval number: 14219; Osaka University, Graduate School of Medicine). Written informed consent was obtained from each

patient.

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Surgical procedure

Representative pre-operative and post-operative radiographs of both procedures are shown in Figure 1.

As for the resection-replacement arthroplasty, most patients (89.3%) were treated by the combination

of Swanson implant replacement of the hallux with the medial approach (10.7% were combined with

open-wedge osteotomy of the first metatarsal bone) [9] and metatarsal head resection osteotomy of the

lesser toes with a dorsal or plantar approach, as previously described [7] (Table 2). In most cases,

medial capsule of the hallux was prepared as rectangular-shaped flap and sutured onto the first

metatarsal bone [9], and adductor hallucis was released from the great toe from the intra-articular side.

As for the joint-preserving arthroplasty, most patients (91.4%) were treated by the combination of

modified Scarf osteotomy of the hallux with the medial longitudinal approach [16] and off-set

shortening osteotomy of the lesser toes with a dorsal longitudinal approach between the second and

third, and the fourth and fifth toe MTP joints, as previously described [17]. The hallux were internally

fixed with AcuTwist® Acutrak® 2.0-mm headless compression screws (Acumed USA, Hillsboro, OR)

or 2.0-3.0-mm cannulated cortical screws. In most cases, medial capsule of the hallux was prepared as

rectangular-shaped flap and sutured to adductor hallucis with inter-positioning technique [18], which

was released from the hallux from the extra-articular side.



In both groups, proximal interphalangeal (PIP) joint resection arthroplasty of the lesser toes with a dorsal approach was added if patients had rigid flexion deformities of the PIP joints, and the lesser toes were temporarily fixed with 1-1.2-mm-diameter Kirschner wires for 2-3 weeks. After removal of the Kirschner wires, the patients were allowed to walk with arch support orthoses, and range of motion exercises were encouraged.

## Statistical analysis

Differences between each study group were tested using the Mann-Whitney U test or the chi-squared test. Changes in each score from pre-operative to post-operative at specified time points within each study group were compared using the nonparametric Wilcoxon signed-rank test. Results are expressed as means  $\pm$  standard error. A P value  $< 0.05$  indicated significance. All tests were performed using IBM SPSS Statistics version 22 software (IBM, Armonk, NY, USA).

## Results

Patients' clinical characteristics of each group when answering post-operative SAFE-Q and pre-operative disease activity are shown in Table 1. Generally, patients with higher pre-operative inflammation (CRP 0.7 vs. 0.3; N.S. [not significant]), longer disease duration (25.1 vs. 21.4 years; N.S.), lower body mass index (19.8 vs. 21.5 kg/m<sup>2</sup>; P<0.01), higher prednisolone dose (2.7 vs. 1.0

mg/day;  $P<0.01$ ), and higher prednisolone usage (67.9 vs. 28.6%;  $P<0.01$ ) tended to be treated with resection-replacement arthroplasty rather than joint-preserving arthroplasty.

Operation-related outcomes are shown in Table 2. On radiographic evaluation, the pre-operative HV angle (35.8 vs. 42.8°), M1M2 angle (11.5 vs. 13.9°), M1M5 angle (34.5 vs. 35.8°) were all similar, although the post-operative HV angle (17.8 vs. 11.3°;  $P<0.05$ ), M1M5 angle (29.8 vs. 23.8°;  $P<0.001$ ), and the recurrence rate of MTP subluxation or dislocation in the lesser toes (53.6% vs. 11.4%;  $P<0.001$ ) were significantly lower in the preserving group than in the resection-replacement group. On the other hand, operation time (120.2 vs. 146.1 minutes;  $P<0.001$ ) was significantly longer in the preserving group than in the resection-replacement group.

Mean pre-operative and post-operative SAFE-Q subscale scores (full score 100 points) are shown in Figure 2. No significant differences were observed in pre-operative subscale scores between the groups. Pain and pain-related [(1) pre-op 36.8 points to post-op 75.0 points vs. (2) 42.2 to 82.6], physical functioning and daily-living [(1) 43.2 to 68.8 vs. (2) 52.7 to 78.1], social functioning [(1) 44.3 to 72.0 vs. (2) 52.5 to 81.9], general health and well-being [(1) 48.4 to 68.4 vs. (2) 45.5 to 84.4], and shoe-related [(1) 30.1 to 50.3 vs. (2) 30.6 to 64.4] scores were all significantly improved in both groups postoperatively ( $P<0.001$ ), while general health and well-being scores ( $P<0.05$ ) and shoe-related scores ( $P<0.05$ ) significantly more improved in the preserving group than in the resection-replacement group.

The pre-operative and post-operative mean scores of each questionnaire item are shown in Figure 3.

The questions that showed significantly higher scores post-operatively in the preserving group than in the resection-replacement group were Q8 (Have you had difficulty in putting on your usual shoes due to foot pain in the past week?) (3.2 vs. 3.8;  $P<0.01$ ), Q11 (How intense was the foot pain you experienced while walking in shoes in the past week?) (2.9 vs. 3.4;  $P<0.05$ ), Q21 (Have you used a walking stick or handrails inside your house due to your foot symptoms in the past week?) (3.0 vs. 3.6;  $P<0.05$ ), Q30 (Have you felt depressed due to your foot symptoms in the past week?) (2.6 vs. 3.4;  $P<0.05$ ), and Q31 (Have you felt frustrated due to your foot symptoms in the past week?) (2.9 vs. 3.6;  $P<0.01$ ).

On the other hand, the questions that showed significantly higher scores pre-operatively in the preserving group than in the resection-replacement group were Q12 (Have you found it difficult to go upstairs due to your foot symptoms in the past week?) (1.4 vs. 2.1;  $P<0.05$ ) and Q17 (Have you found it difficult to walk uphill due to your foot symptoms in the past week?) (1.5 vs. 2.2;  $P<0.05$ ), although they showed no significant difference post-operatively between the groups.

## Discussion

As far as we know, this is the first report that demonstrated differences in clinical outcomes between these two surgical procedures using a patient-based outcome instrument, SAFE-Q [15]. The present

result showed that, with respect to patient-based and radiographic outcomes, joint-preserving arthroplasty resulted in better clinical outcomes than resection-replacement arthroplasty.

Loss of joint function owing to the dislocation of the proximal phalanges is considered a primary cause of painful plantar callosity of MTP joints [19]. In addition, hammer and claw toe deformities of the lesser toes are often associated with painful dorsal callosities in the PIP joints with low instep shoes [20]. Moreover, Laroche et al. showed that walking velocity and stride length are associated with MTP joint function [21], suggesting that preventing the recurrence of MTP joint dislocation is beneficial for both pain management and gait performance.

In the present study, the preserving group resulted in a lower HV angle and less MTP joint subluxation or dislocation than the resection-replacement group, which may be reflected in the better outcomes for Q8 (Have you had difficulty in putting on your usual shoes due to foot pain in the past week?), Q11 (How intense was the foot pain you experienced while walking in shoes in the past week?), and Q21 (Have you used a walking stick or handrails inside your house due to your foot symptoms in the past week?).

In addition, previous reports showed that joint deformity and joint pain were independently associated with high depressive symptoms [22, 23], which may account for Q30 (Have you felt depressed due to your foot symptoms in the past week?) and Q31 (Have you felt frustrated due to your foot symptoms in the past week?). Several reasons can be considered to explain these finding. First, toe deformities of

RA are caused by an imbalance between the intrinsic and extrinsic muscles due to the arthritis [20].

Since the MTP joints are like ball-and-socket joints, preserving the metatarsal head may be beneficial

for joint stabilization. Second, in joint-preserving arthroplasty, we usually use inter-positioning

technique suturing the medial capsule flap with adductor hallucis, which is released from the great toe

from the extra-articular side [18]. This may provide varus tension to the MTP joints, which may avoid

recurrence of hallux valgus deformity.

However, several questionnaire items were difficult to improve on the post-operative score with both

operations, such as Q9 (Do you find it difficult to find comfortable shoes due to your foot symptoms?),

Q20 (Have you found it difficult to stand on your toes due to your foot symptoms in the past week?),

and Q34 (Have you had difficulty in putting on high-fashion or formal shoes in the past month?)

(Fig.3). A previous report showed that shoe-related subscale and physical functioning and daily living

subscale scores of SAFE-Q may reflect the consequences of women wearing high-heeled footwear and

women's more fashion-oriented attitude toward shoes [15]. Generally, high-heeled and

fashion-oriented footwear of women requires high-dorsiflexion of the MTP joints. Niki et al. reported

that, in joint-preserving surgery of RA, patients with pre-operative destruction of MTP joints more

than Larsen's grade III tended to show restricted range of motion [5]. Some inventive ideas may be

required to improve these outcomes, such as obtaining sufficient metatarsal shortening to acquire

appropriate MTP joints pressure after reduction and early removal of Kirschner wires with aggressive

dorsiflexion exercises.

There are several limitations in this study. First, the selection of the methods was dependent on each surgeon's discretion and not randomized, so personal preference may exist. Second, although fair clinical outcomes of hallux MTP joint arthrodesis with metatarsal head resection of lesser toes have been reported [7,8], this method was not included in this study because of the small number of the patients. Third, for the pre-operative SAFE-Q, 53.6% (15/28) of the resection-replacement group and 40.0% (14/35) of the preserving group were asked retrospectively. Fourth, the operation methods of each group were not completely integrated.

In conclusion, with respect to patient-based and radiographic outcomes, joint-preserving arthroplasty resulted in better clinical outcomes than resection-replacement arthroplasty in forefoot surgery for patients with RA.

#### **Conflict of interest**

None.

## Figure Legends

**Figure 1.** The pre-operative and post-operative radiographs of (a) a 63-year-old woman who underwent metatarsal head resection-replacement arthroplasty (Swanson implant replacement of the hallux metatarsophalangeal joint and metatarsal head resection of the lesser toes), and (b) a 68-year-old woman who underwent metatarsophalangeal joint-preserving arthroplasty (modified Scarf osteotomy with inter-positioning technique of the medial capsule of the hallux and off-set shortening osteotomy of the lesser toes).

**Figure 2.** Mean pre-operative and post-operative SAFE-Q subscale scores (full score 100 points) of both resection-replacement group and preserving group. Mean values of (a) Pain and pain-related scores, (b) Physical functioning and daily-living scores, (c) Social functioning scores, (d) General health and well-being scores, and (e) Shoe-related scores. Bars indicate standard errors.

\*\*\* P < 0.001, pre-op vs. post-op. # P < 0.05, resection-replacement vs. preserving.

**Figure 3.** Mean pre-operative and post-operative SAFE-Q scores for each question (full score 4 points) for both resection-replacement group and preserving group. Bars indicate standard errors.

\* P < 0.05, \*\* P < 0.01, resection-replacement vs. preserving post-op. # P < 0.05, resection-replacement vs. preserving pre-op.

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1     Table 1. Clinical characteristics of each group when answering post-operative SAFE-Q

Variable	Resection-replacement (n=28)	Preserving (n=35)	P value
Age, (mean ± SE years)	63.8±1.6	63.1±2.1	N.S.
Gender, Females (%)	96.4	94.3	N.S.
Body mass index (kg/m <sup>2</sup> )	19.8±0.5	21.5±0.4	< 0.01
Duration of disease (years)	25.1±1.9	21.4±1.7	N.S.
Postoperative duration (years)	4.2±0.6	3.6±0.6	N.S.
Steinbrocker' s stage (n)	III(n=2) IV(n=26)	III(n=6) IV(n=29)	N.S.
Steinbrocker' s functional class (n)	II (n=13) III(n=15)	II (n=11) III(n=23) IV(n=1)	N.S.
RF positivity (%)	91.7	73.1	N.S.
ACPA positivity (%)	93.8	72.7	N.S.
CRP (mg/dl)	0.7±0.2	0.3±0.1	N.S.
Pre-op MMP-3 (ng/ml)	114.9±13.0	79.1±11.0	N.S.
DAS28-CRP	2.6±0.1	2.4±0.1	N.S.
CRP (mg/dl)	0.5±0.1	0.2±0.1	N.S.
Post-op MMP-3 (ng/ml)	108.8±12.2	77.0±13.6	N.S.
DAS28-CRP	2.2±0.1	2.1±0.1	N.S.
Prednisolone dose (mg/day)	2.7±0.5	1.0±0.4	< 0.01
Prednisolone usage (%)	67.9	28.6	< 0.01
MTX dose (mg/week)	3.9±0.7	3.6±0.6	N.S.
MTX usage (%)	67.9	54.3	N.S.
Biologics usage (%)	28.6	42.9	N.S.
Biologics (n)	TCZ(4) ETN(3) ABT(1)	TCZ(10) ETN(3) ABT(1) GOL(1)	-

2     Mean ± Standard Error (SE), unless otherwise noted. N.S., not significant;  
3     RF, Rheumatoid factor; ACPA, Anti- cyclic citrullinated peptide antibody; CRP, C-reactive protein;  
4     MMP-3, Matrix metalloproteinase-3; DAS28-CRP, Disease activity score assessing 28 joints with CRP;  
5     MTX, Methotrexate; TCZ, tocilizumab; ETN, etanercept; ABT, abatacept; GOL, golimumab.  
6     Differences between the groups were determined by Mann-Whitney U-test or chi-squared test.

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11 Table 2. Operation-related outcomes

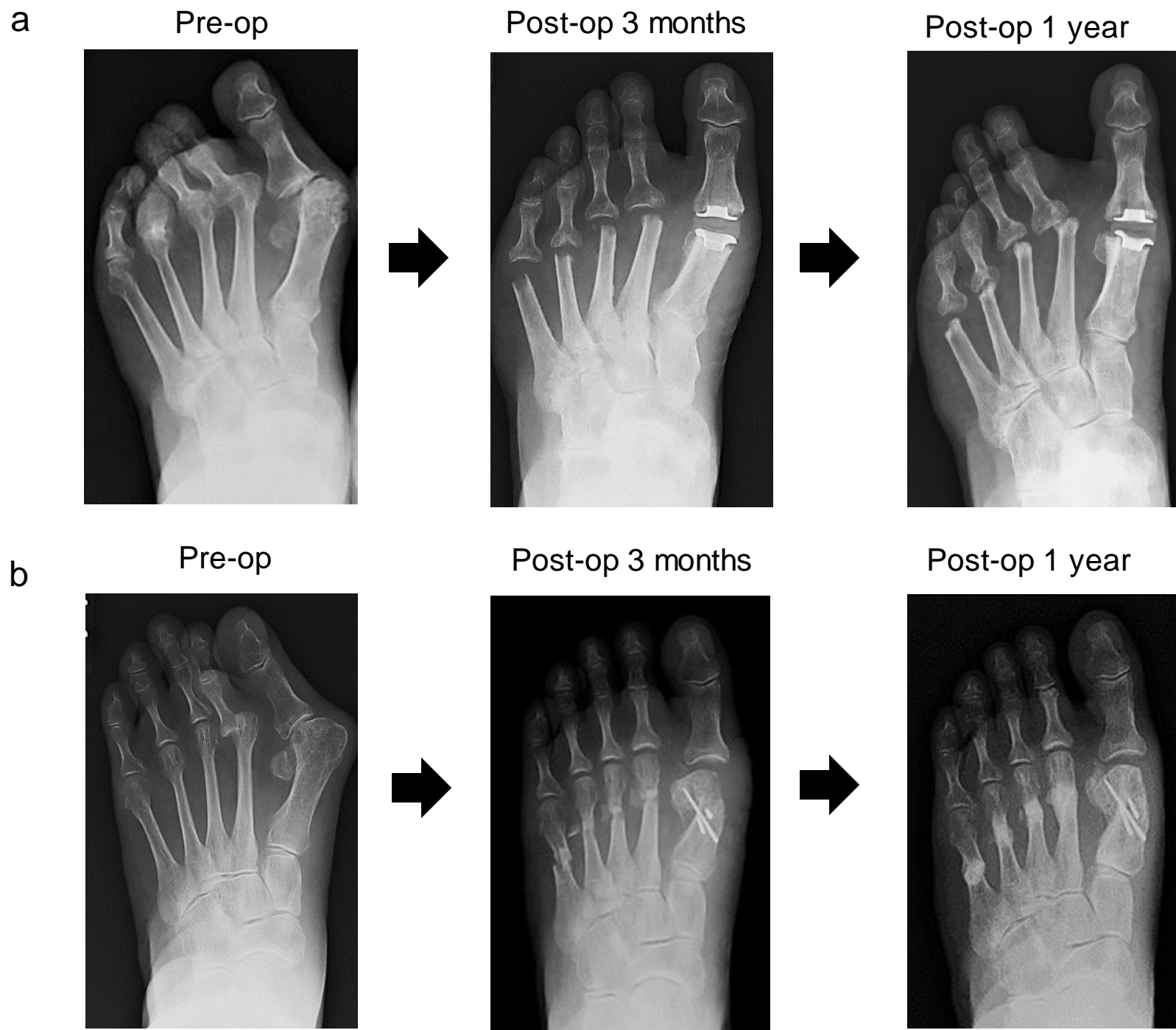
Variable		Resection-replacement (n=28)	Preserving (n=35)	P value
Operation methods (n)	Hallux	Swanson implant (n=26) Resection (n=2)	Modified Scarf (n=32) Modified Mann (n=2) Lapidus (n=1)	-
	Lesser toes	Resection (n=28)	Off-set osteotomy (n=35)	
	Previous lower limb operation (n)	TKA (n=9) TAA (n=1)	TKA (n=7) TAA (n=3) arthrodesis (ankle n=1, subtalar n=3)	-
Operation time (minutes)		120.2±4.0	146.1±5.0	< 0.001
Delayed wound healing (%)		0	11.4	N.S.
Swanson implant breakdown (%)		12.0	-	-
Implant infection and removal (%)		3.6	0	N.S.
Pre-op (degree)	HV angle	35.8±3.4	42.8±2.9	N.S.
	M1M2 angle	11.5±1.1	13.9±0.7	N.S.
	M1M5 angle	34.5±1.2	35.8±1.0	N.S.
Post-op (degree)	HV angle	17.8±1.5	11.3±1.7	< 0.05
	M1M2 angle	7.6±0.7	8.4±0.7	N.S.
	M1M5 angle	29.8±1.3	23.8±0.9	< 0.001
Recurrence of lesser toes MTP subluxation or dislocation (%)		53.6	11.4	< 0.001

12 Mean ± Standard Error (SE), unless otherwise noted. N.S., not significant;

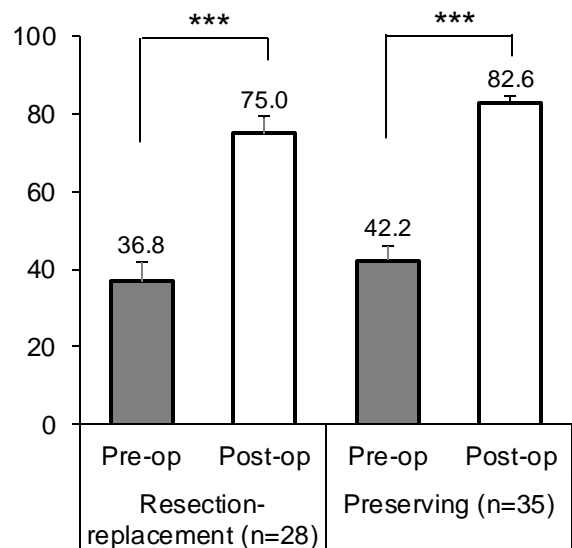
13 TKA, Total knee arthroplasty; TAA, Total ankle arthroplasty; HV, Hallux valgus; M1M2, first metatarsal  
14 and second metatarsal; M1M5, first metatarsal and fifth metatarsal.

15 Differences between the groups were determined by Mann-Whitney U-test or chi-squared test.

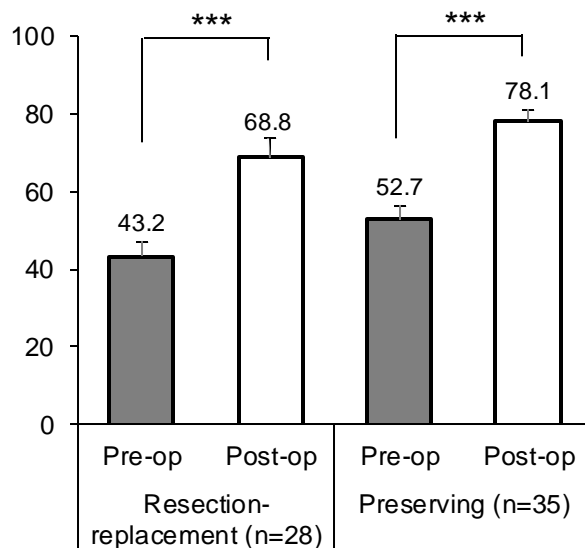
Figure



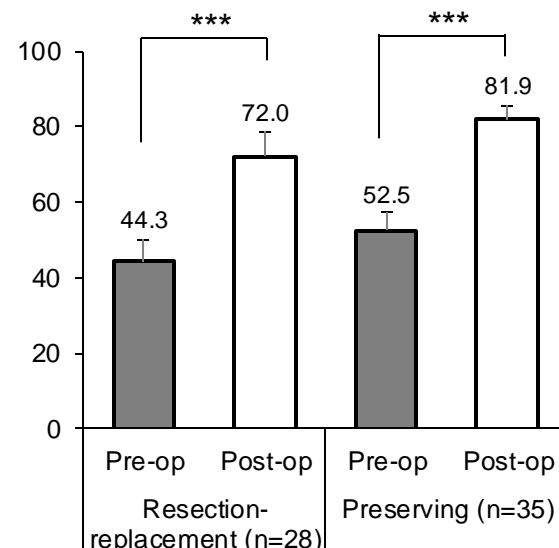
**a** Pain and pain-related



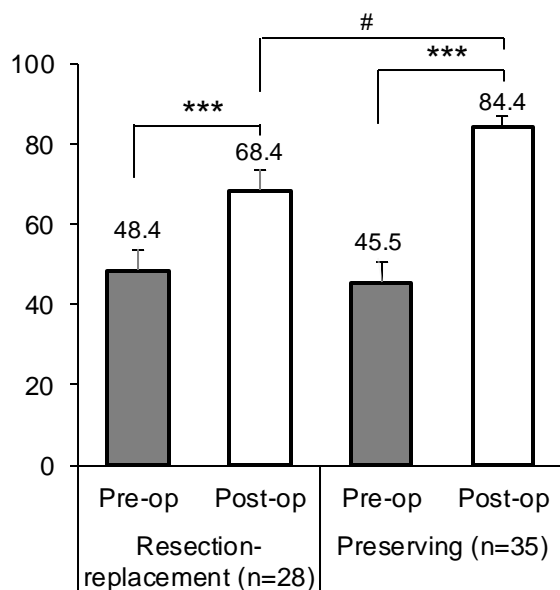
**b** Physical functioning and daily-living



**c** Social functioning



**d** General health and well-being



**e** Shoe-related

