

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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1 1 **Original Article**

7 3 ***Title:***

4 4 Comparison of a self-administered foot evaluation questionnaire (SAFE-Q) between joint-preserving
5 5 arthroplasty and resection-replacement arthroplasty in forefoot surgery for patients with rheumatoid
6 6 arthritis

24 8 ***Authors:***

27 9 Kosuke Ebina^{1*}, Makoto Hirao¹, Jun Hashimoto², Akihide Nampei³, Kenrin Shi⁴, Tetsuya Tomita⁵,
30 10 Kazuma Futai¹, Yasuo Kunugiza⁶, Takaaki Noguchi¹, and Hideki Yoshikawa¹

37 12 ***Affiliations:***

41 13 ¹Department of Orthopaedic Surgery, Osaka University Graduate School of Medicine

44 14 ²Department of Rheumatology, National Hospital Organization, Osaka-Minami Medical Center

48 15 ³Department of Orthopaedic Surgery, National Hospital Organization, Osaka-Minami Medical Center

51 16 ⁴Department of Rheumatology, Yukioka Hospital

54 17 ⁵Department of Orthopaedic Biomaterial Science, Osaka University Graduate School of Medicine

57 18 ⁶Department of Orthopaedic Surgery, Japan Community Healthcare Organization, Hoshigaoka

1 19 Medical Center

4 20

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14 23 arthritis, SAFE-Q

18 24

21 25 ****Corresponding author:***

24 26 Kosuke Ebina, MD, PhD, Assistant Professor

27 27 Department of Orthopaedic Surgery, Osaka University Graduate School of Medicine,

31 28 2-2 Yamada-oka, Suita, Osaka 565-0871, Japan

34 29 Phone: +81-6-6879-3552; Fax: +81-6-6879-3559

37 30 E-mail: k-ebina@umin.ac.jp

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

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1 36 **Abstract**

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4 37 Objectives

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7 38 To clarify the difference of patient-based outcome between joint-preserving arthroplasty and
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11 39 resection-replacement arthroplasty in forefoot surgery for patients with rheumatoid arthritis (RA).

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14 40 Methods

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17 41 A total of 63 feet of 49 RA patients who underwent forefoot surgery were asked to answer
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21 42 pre-operative and post-operative self-administered foot evaluation questionnaire (SAFE-Q). Patients
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24 43 were treated with either (1) metatarsal head resection-replacement arthroplasty (28 feet, post-operative
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27 44 mean age 63.8 years, follow-up 4.2 years, DAS28-CRP 2.2) or (2) metatarsophalangeal
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31 45 joint-preserving arthroplasty (35 feet, post-operative mean age 63.1 years, follow-up 3.6 years,
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34 46 DAS28-CRP 2.1) at each surgeon's discretion.

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37 47 Results

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41 48 Mean pre-operative and post-operative subscale scores of SAFE-Q of group (1) and (2) were as
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44 49 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],
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48 50 physical functioning and daily-living [(1) 43.2 to 68.8 vs. (2) 52.7 to 78.1], social functioning [(1) 44.3
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51 51 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
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54 52 shoe-related [(1) 30.1 to 50.3 vs. (2) 30.6 to 64.4]. Both general health and well-being subscale scores
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57 53 (P<0.05) and shoe-related subscale scores (P<0.05) were significantly more improved in group (2)

1 54 compared to group (1).

4 55 Conclusions:

7 56 Joint-preserving arthroplasty resulted in better patient-based outcomes than resection-replacement
10 57 arthroplasty.

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17 59 **Introduction**

21 60 Rheumatoid arthritis (RA) is frequently associated with forefoot arthritis and painful deformities

24 61 including hallux valgus (HV), dorsal dislocation of the metatarsophalangeal (MTP) joints, and

28 62 hammer toe deformity of the lesser toes [1-3]. With recent advances in the pharmacological treatment

31 63 of RA, such as biologic agents, global forefoot deformities tend to be associated with less erosive

34 64 changes [4], which has resulted in a trend toward joint-preserving arthroplasty rather than conventional

37 65 resection arthroplasty of forefoot deformities [5, 6]. However, there is no reliable evidence

41 66 demonstrating that joint-preservation has an advantage over resection, since fair clinical outcomes of

44 67 both resection-replacement arthroplasty [7-9] and joint-preserving arthroplasty [5, 10-12] have been

48 68 reported. In addition, as far as we know, there are no previous reports that assessed these operations'

51 69 clinical outcomes by a patient-based outcome instrument, which is recently becoming popular in

54 70 various orthopedic diseases and surgeries [13, 14]. The Japanese Society for Surgery of the Foot

57 71 (JSSF) has recently developed a patient-based self-administered foot evaluation questionnaire

1 72 (SAFE-Q) [15]. The main body of the outcome instrument consists of 34 questionnaire items, which
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4 73 provide five subscale scores (1: Pain and Pain-Related; 2: Physical Functioning and Daily Living; 3:
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7 74 Social Functioning; 4: Shoe-Related; and 5: General Health and Well-Being), and each subscale score
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11 75 ranges from 0 to 100 points. A previous report demonstrated that these subscale scores were all lowest
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14 76 in patients with RA compared to other foot diseases, and the Pain and Pain-Related subscale was more
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17 77 responsive than the SF-36 Bodily Pain subscale [15]. The purpose of this study was to evaluate and
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21 78 compare the mid-term clinical outcomes of both resection-replacement arthroplasty and
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24 79 joint-preserving arthroplasty for forefoot deformities in patients with RA using a patient-based
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27 80 outcome instrument.
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32 33 34 82 **Materials and methods**

35 36 37 83 **Patients and clinical assessment**

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41 84 A total of 63 feet of 49 patients with RA (46 women and 3 men) who underwent forefoot surgery in 3
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44 85 institutes by 8 senior rheumatoid surgeons from January 2000 to December 2015 were enrolled.
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47 86 Patients were treated with either (1) metatarsal head resection-replacement arthroplasty (mainly
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51 87 Swanson implant replacement of the hallux MTP joint and metatarsal head resection of the lesser toes)
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54 88 [Resection-replacement; 28 feet of 20 patients, post-operative mean age 63.8 years, follow-up 4.2
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57 89 years (range, 0.5-15 years), Disease activity score assessing 28 joints with CRP (DAS28-CRP) 2.2
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1 90 (range, 1.1-3.6)] or (2) MTP joint-preserving arthroplasty (mainly modified Scarf osteotomy of the
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4 91 hallux and off-set shortening osteotomy of the lesser toes). [Preserving; 35 feet of 29 patients,
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7 92 post-operative mean age 63.1 years, follow-up 3.6 years (range, 0.5-15 years), DAS28-CRP 2.1 (range,
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10 93 1.5-2.8)] at the discretion of each surgeon. Patients were radiographically evaluated and asked to
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14 94 answer the pre-operative and post-operative SAFE-Q, and the clinical characteristics of each group
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17 95 when asked to answer post-operative SAFE-Q are shown in Table 1. For the pre-operative SAFE-Q,
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21 96 53.6% (15/28) of the resection-replacement group and 40.0% (14/35) of the preserving group were
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24 97 administered the questionnaire retrospectively, since the SAFE-Q was published on January 9, 2013.
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27 98 The questions about sports activity (Q35-43) were not included this study. The hallux valgus angle
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31 99 (HVA), first metatarsal and second metatarsal (M1M2) angle, first metatarsal and fifth metatarsal
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34 100 (M1M5) angle, and the recurrence of lesser toe MTP joint subluxation or dislocation were defined by
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37 101 anteroposterior weight-bearing radiographs which were performed pre-operatively and
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41 102 post-operatively when SAFE-Q was administered, as previously described [7]. Briefly, if the axis of
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44 103 the proximal phalanx was displaced by one diaphyseal width or less, it was defined as subluxated, and
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47 104 if it was displaced more than one diaphyseal width, it was defined as dislocated.
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51 105 This study was conducted in accordance with the ethical standards of the Declaration of Helsinki, and
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54 106 was approved by the Institutional Ethical Review Board at each center (approval number: 14219;
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57 107 Osaka University, Graduate School of Medicine). Written informed consent was obtained from each
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1 108 patient.
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7 110 Surgical procedure
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11 111 Representative pre-operative and post-operative radiographs of both procedures are shown in Figure 1.
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14 112 As for the resection-replacement arthroplasty, most patients (89.3%) were treated by the combination
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17 113 of Swanson implant replacement of the hallux with the medial approach (10.7% were combined with
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21 114 open-wedge osteotomy of the first metatarsal bone) [9] and metatarsal head resection osteotomy of the
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24 115 lesser toes with a dorsal or plantar approach, as previously described [7] (Table 2). In most cases,
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27 116 medial capsule of the hallux was prepared as rectangular-shaped flap and sutured onto the first
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31 117 metatarsal bone [9], and adductor hallucis was released from the great toe from the intra-articular side.
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34 118 As for the joint-preserving arthroplasty, most patients (91.4%) were treated by the combination of
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37 119 modified Scarf osteotomy of the hallux with the medial longitudinal approach [16] and off-set
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41 120 shortening osteotomy of the lesser toes with a dorsal longitudinal approach between the second and
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44 121 third, and the fourth and fifth toe MTP joints, as previously described [17]. The hallux were internally
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47 122 fixed with AcuTwist® Acutrak® 2.0-mm headless compression screws (Acumed USA, Hillsboro, OR)
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51 123 or 2.0-3.0-mm cannulated cortical screws. In most cases, medial capsule of the hallux was prepared as
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54 124 rectangular-shaped flap and sutured to adductor hallucis with inter-positioning technique [18], which
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57 125 was released from the hallux from the extra-articular side.
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1 126 In both groups, proximal interphalangeal (PIP) joint resection arthroplasty of the lesser toes with a
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4 127 dorsal approach was added if patients had rigid flexion deformities of the PIP joints, and the lesser
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7 128 toes were temporarily fixed with 1-1.2-mm-diameter Kirschner wires for 2-3 weeks. After removal of
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11 129 the Kirschner wires, the patients were allowed to walk with arch support orthoses, and range of motion
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14 130 exercises were encouraged.

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21 132 Statistical analysis
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24 133 Differences between each study group were tested using the Mann-Whitney U test or the chi-squared
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27 134 test. Changes in each score from pre-operative to post-operative at specified time points within each
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31 135 study group were compared using the nonparametric Wilcoxon signed-rank test. Results are expressed
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34 136 as means \pm standard error. A P value < 0.05 indicated significance. All tests were performed using
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37 137 IBM SPSS Statistics version 22 software (IBM, Armonk, NY, USA).

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44 139 **Results**
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47 140 Patients' clinical characteristics of each group when answering post-operative SAFE-Q and
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51 141 pre-operative disease activity are shown in Table 1. Generally, patients with higher pre-operative
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54 142 inflammation (CRP 0.7 vs. 0.3; N.S. [not significant]), longer disease duration (25.1 vs. 21.4 years;
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57 143 N.S.), lower body mass index (19.8 vs. 21.5 kg/m²; P<0.01), higher prednisolone dose (2.7 vs. 1.0
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1 144 mg/day; $P<0.01$), and higher prednisolone usage (67.9 vs. 28.6%; $P<0.01$) tended to be treated with
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4 145 resection-replacement arthroplasty rather than joint-preserving arthroplasty.
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7 146 Operation-related outcomes are shown in Table 2. On radiographic evaluation, the pre-operative HV
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11 147 angle (35.8 vs. 42.8°), M1M2 angle (11.5 vs. 13.9°), M1M5 angle (34.5 vs. 35.8°) were all similar,
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14 148 although the post-operative HV angle (17.8 vs. 11.3°; $P<0.05$), M1M5 angle (29.8 vs. 23.8°; $P<0.001$),
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17 149 and the recurrence rate of MTP subluxation or dislocation in the lesser toes (53.6% vs. 11.4%;
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21 150 $P<0.001$) were significantly lower in the preserving group than in the resection-replacement group. On
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24 151 the other hand, operation time (120.2 vs. 146.1 minutes; $P<0.001$) was significantly longer in the
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27 152 preserving group than in the resection-replacement group.
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31 153 Mean pre-operative and post-operative SAFE-Q subscale scores (full score 100 points) are shown in
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34 154 Figure 2. No significant differences were observed in pre-operative subscale scores between the
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37 155 groups. Pain and pain-related [(1) pre-op 36.8 points to post-op 75.0 points vs. (2) 42.2 to 82.6],
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41 156 physical functioning and daily-living [(1) 43.2 to 68.8 vs. (2) 52.7 to 78.1], social functioning [(1) 44.3
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44 157 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
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47 158 shoe-related [(1) 30.1 to 50.3 vs. (2) 30.6 to 64.4] scores were all significantly improved in both
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51 159 groups postoperatively ($P<0.001$), while general health and well-being scores ($P<0.05$) and
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54 160 shoe-related scores ($P<0.05$) significantly more improved in the preserving group than in the
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57 161 resection-replacement group.
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1 162 The pre-operative and post-operative mean scores of each questionnaire item are shown in Figure 3.
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4 163 The questions that showed significantly higher scores post-operatively in the preserving group than in
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7 164 the resection-replacement group were Q8 (Have you had difficulty in putting on your usual shoes due
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11 165 to foot pain in the past week?) (3.2 vs. 3.8; $P<0.01$), Q11 (How intense was the foot pain you
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14 166 experienced while walking in shoes in the past week?) (2.9 vs. 3.4; $P<0.05$), Q21 (Have you used a
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17 167 walking stick or handrails inside your house due to your foot symptoms in the past week?) (3.0 vs. 3.6;
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21 168 $P<0.05$), Q30 (Have you felt depressed due to your foot symptoms in the past week?) (2.6 vs. 3.4;
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24 169 $P<0.05$), and Q31 (Have you felt frustrated due to your foot symptoms in the past week?) (2.9 vs. 3.6;
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27 170 $P<0.01$).
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31 171 On the other hand, the questions that showed significantly higher scores pre-operatively in the
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34 172 preserving group than in the resection-replacement group were Q12 (Have you found it difficult to go
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37 173 upstairs due to your foot symptoms in the past week?) (1.4 vs. 2.1; $P<0.05$) and Q17 (Have you found
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41 174 it difficult to walk uphill due to your foot symptoms in the past week?) (1.5 vs. 2.2; $P<0.05$), although
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44 175 they showed no significant difference post-operatively between the groups.
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51 177 **Discussion**

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54 178 As far as we know, this is the first report that demonstrated differences in clinical outcomes between
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57 179 these two surgical procedures using a patient-based outcome instrument, SAFE-Q [15]. The present
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1 180 result showed that, with respect to patient-based and radiographic outcomes, joint-preserving
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4 181 arthroplasty resulted in better clinical outcomes than resection-replacement arthroplasty.
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7 182 Loss of joint function owing to the dislocation of the proximal phalanges is considered a primary
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11 183 cause of painful plantar callosity of MTP joints [19]. In addition, hammer and claw toe deformities of
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14 184 the lesser toes are often associated with painful dorsal callosities in the PIP joints with low instep
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17 185 shoes [20]. Moreover, Laroche et al. showed that walking velocity and stride length are associated with
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21 186 MTP joint function [21], suggesting that preventing the recurrence of MTP joint dislocation is
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24 187 beneficial for both pain management and gait performance.
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27 188 In the present study, the preserving group resulted in a lower HV angle and less MTP joint subluxation
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31 189 or dislocation than the resection-replacement group, which may be reflected in the better outcomes for
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34 190 Q8 (Have you had difficulty in putting on your usual shoes due to foot pain in the past week?), Q11
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37 191 (How intense was the foot pain you experienced while walking in shoes in the past week?), and Q21
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41 192 (Have you used a walking stick or handrails inside your house due to your foot symptoms in the past
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44 193 week?).
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47 194 In addition, previous reports showed that joint deformity and joint pain were independently associated
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51 195 with high depressive symptoms [22, 23], which may account for Q30 (Have you felt depressed due to
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54 196 your foot symptoms in the past week?) and Q31 (Have you felt frustrated due to your foot symptoms
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57 197 in the past week?). Several reasons can be considered to explain these finding. First, toe deformities of
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1 198 RA are caused by an imbalance between the intrinsic and extrinsic muscles due to the arthritis [20].

4 199 Since the MTP joints are like ball-and-socket joints, preserving the metatarsal head may be beneficial

8 200 for joint stabilization. Second, in joint-preserving arthroplasty, we usually use inter-positioning

11 201 technique suturing the medial capsule flap with adductor hallucis, which is released from the great toe

14 202 from the extra-articular side [18]. This may provide varus tension to the MTP joints, which may avoid

18 203 recurrence of hallux valgus deformity.

21 204 However, several questionnaire items were difficult to improve on the post-operative score with both

24 205 operations, such as Q9 (Do you find it difficult to find comfortable shoes due to your foot symptoms?),

28 206 Q20 (Have you found it difficult to stand on your toes due to your foot symptoms in the past week?),

31 207 and Q34 (Have you had difficulty in putting on high-fashion or formal shoes in the past month?)

34 208 (Fig.3). A previous report showed that shoe-related subscale and physical functioning and daily living

38 209 subscale scores of SAFE-Q may reflect the consequences of women wearing high-heeled footwear and

41 210 women's more fashion-oriented attitude toward shoes [15]. Generally, high-heeled and

44 211 fashion-oriented footwear of women requires high-dorsiflexion of the MTP joints. Niki et al. reported

48 212 that, in joint-preserving surgery of RA, patients with pre-operative destruction of MTP joints more

51 213 than Larsen's grade III tended to show restricted range of motion [5]. Some inventive ideas may be

54 214 required to improve these outcomes, such as obtaining sufficient metatarsal shortening to acquire

58 215 appropriate MTP joints pressure after reduction and early removal of Kirschner wires with aggressive

1 216 dorsiflexion exercises.
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4 217 There are several limitations in this study. First, the selection of the methods was dependent on each
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7 218 surgeon's discretion and not randomized, so personal preference may exist. Second, although fair
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11 219 clinical outcomes of hallux MTP joint arthrodesis with metatarsal head resection of lesser toes have
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14 220 been reported [7,8], this method was not included in this study because of the small number of the
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17 221 patients. Third, for the pre-operative SAFE-Q, 53.6% (15/28) of the resection-replacement group and
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21 222 40.0% (14/35) of the preserving group were asked retrospectively. Fourth, the operation methods of
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24 223 each group were not completely integrated.

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27 224 In conclusion, with respect to patient-based and radiographic outcomes, joint-preserving arthroplasty
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31 225 resulted in better clinical outcomes than resection-replacement arthroplasty in forefoot surgery for
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34 226 patients with RA.

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41 228 **Conflict of interest**

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1 232 **Figure Legends**

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4 233 **Figure 1.** The pre-operative and post-operative radiographs of (a) a 63-year-old woman who
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7 234 underwent metatarsal head resection-replacement arthroplasty (Swanson implant replacement of the
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11 235 hallux metatarsophalangeal joint and metatarsal head resection of the lesser toes), and (b) a
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14 236 68-year-old woman who underwent metatarsophalangeal joint-preserving arthroplasty (modified Scarf
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17 237 osteotomy with inter-positioning technique of the medical capsule of the hallux and off-set shortening
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21 238 osteotomy of the lesser toes).

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27 240 **Figure 2.** Mean pre-operative and post-operative SAFE-Q subscale scores (full score 100 points) of
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31 241 both resection-replacement group and preserving group. Mean values of (a) Pain and pain-related
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34 242 scores, (b) Physical functioning and daily-living scores, (c) Social functioning scores, (d) General
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37 243 health and well-being scores, and (e) Shoe-related scores. Bars indicate standard errors.

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41 244 *** P < 0.001, pre-op vs. post-op. # P < 0.05, resection-replacement vs. preserving.

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47 246 **Figure 3.** Mean pre-operative and post-operative SAFE-Q scores for each question (full score 4
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51 247 points) for both resection-replacement group and preserving group. Bars indicate standard errors.

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54 248 * P < 0.05, ** P < 0.01, resection-replacement vs. preserving post-op. # P < 0.05,
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57 249 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 ²)	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.

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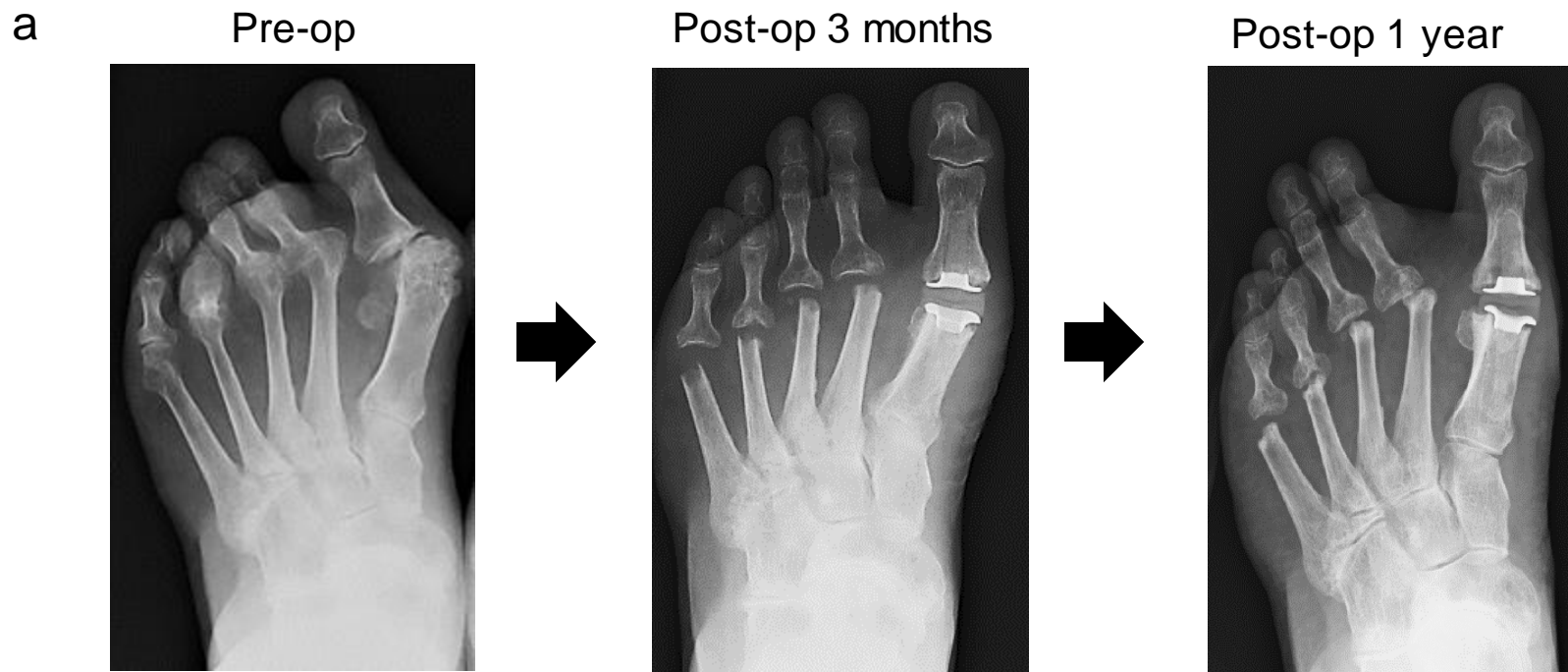
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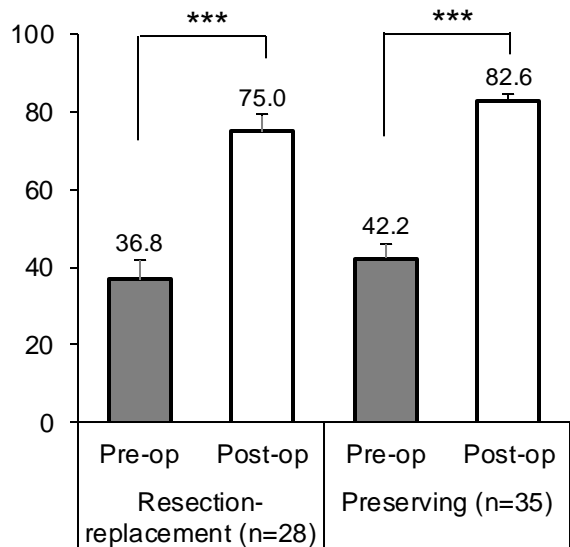
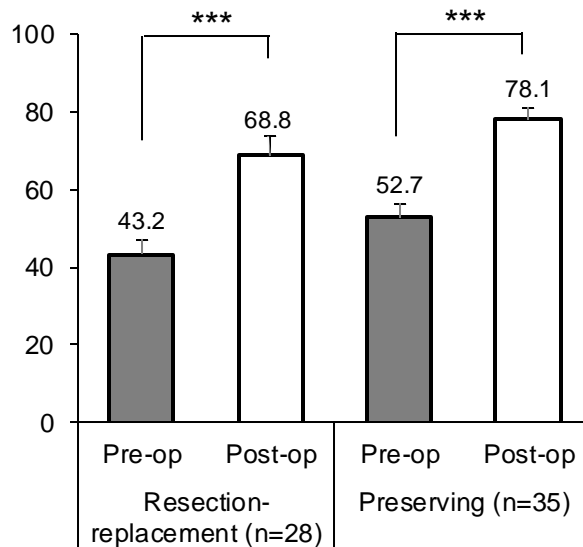
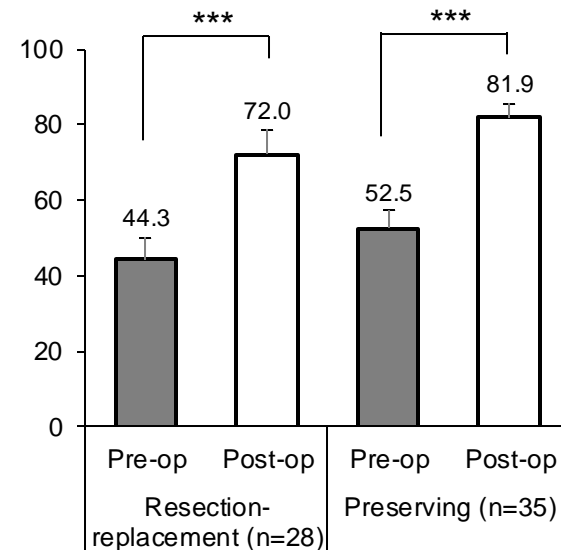
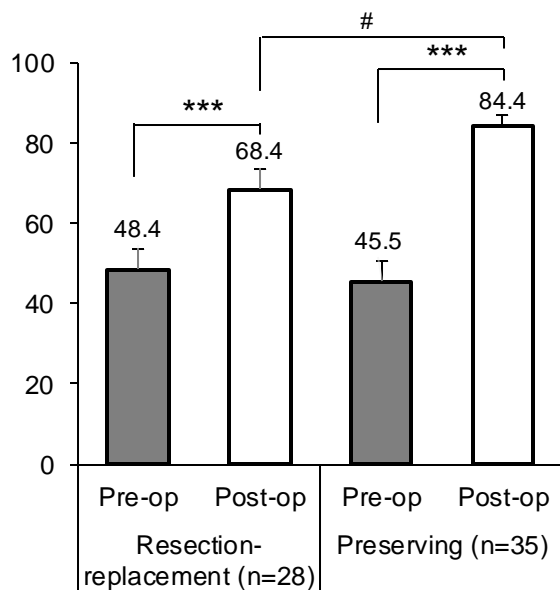
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Figure



a Pain and pain-related**b** Physical functioning and daily-living**c** Social functioning**d** General health and well-being**e** Shoe-related