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## Who, if anyone, may benefit from a total hip arthroplasty after a displaced femoral neck fracture?

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## ■ HIP

# Who, if anyone, may benefit from a total hip arthroplasty after a displaced femoral neck fracture?

## A POST HOC SUBGROUP ANALYSIS OF THE HEALTH TRIAL

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### Aims

The aim of this study was to explore the functional results in a fitter subgroup of participants in the Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemiarthroplasty (HEALTH) trial to determine whether there was an advantage of total hip arthroplasty (THA) versus hemiarthroplasty (HA) in this population.

### Methods

We performed a post hoc exploratory analysis of a fitter cohort of patients from the HEALTH trial. Participants were aged over 50 years and had sustained a low-energy displaced femoral neck fracture (FNF). The fittest participant cohort was defined as participants aged 70 years or younger, classified as American Society of Anesthesiologists grade I or II, independent walkers prior to fracture, and living at home prior to fracture. Multilevel models were used to estimate the effect of THA versus HA on functional outcomes. In addition, a sensitivity analysis of the definition of the fittest participant cohort was performed.

### Results

There were 143 patients included in the fittest cohort. Mean age was 66 years (SD 4.5) and 103 were female (72%). No clinically relevant differences were found between the treatment groups in the primary and sensitivity analyses.

### Conclusion

This analysis found no differences in functional outcomes between HA and THA within two years of displaced low-energy FNF in a subgroup analysis of the fittest HEALTH patients. These findings suggest that very few patients above 50 years of age benefit in a clinically meaningful way from a THA versus a HA early after injury.

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**Keywords:** Femoral neck fracture, Health-related quality of life, Total hip arthroplasty, Hemiarthroplasty

### Introduction

A displaced femoral neck fracture (FNF) is a dramatic and potentially life-changing event. Despite reports of reduced incidence from several countries, the number of hip fractures is expected to increase due to an ageing population.<sup>1</sup> The treatment goal is to allow the patient to regain independence and function as quickly as possible, without the need for further surgeries. Influential guidelines by the National Institute for Health and Care Excellence

(NICE) and American Academy of Orthopaedic Surgeons (AAOS) recommend arthroplasty as the surgical treatment of choice for displaced FNFs in the elderly.<sup>2,3</sup> Arthroplasty offers a low risk of major complications and good functional results.<sup>4</sup> A total hip arthroplasty (THA) has been recommended over a hemiarthroplasty (HA) typically for a healthier subset of patients with longer life expectancy. According to the NICE guidelines from 2017, patients who are independent walkers, not cognitively impaired,

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**Table 1.** Patient characteristics.

| Characteristic                                  | Fittest cohort (n = 143) |                 | Other patients (n = 1,298) |                  |
|---|--------------------------|-----------------|----------------------------|------------------|
|   | THA (n = 73)             | HA (n = 70)     | THA (n = 645)              | HA (n = 653)     |
| Mean age, yrs (SD)                              | 65.7 (4.3)               | 65.8 (4.7)      | 80.6 (7.2)                 | 79.9 (7.8)       |
| <b>Age, n (%)</b>                               |                          |                 |                            |                  |
| 50 to 70 yrs                                    | 73 (100.0)               | 70 (100.0)      | 63 (9.8)                   | 248 (38.0)       |
| 71 to 80 yrs                                    | 0 (0.0)                  | 0 (0.0)         | 249 (38.6)                 | 324 (49.6)       |
| ≥ 81 yrs  | 0 (0.0)                  | 0 (0.0)         | 333 (51.6)                 | 449 (68.8)       |
| <b>Sex, n (%)</b>                               |                          |                 |                            |                  |
| Male  | 20 (27.4)                | 19 (27.1)       | 188 (29.1)                 | 204 (31.2)       |
| Female  | 53 (72.6)                | 50 (71.4)       | 457 (70.9)                 | 449 (68.8)       |
| <b>Ethnicity, n (%)</b>                         |                          | <b>(n = 69)</b> | <b>(n = 643)</b>           | <b>(n = 652)</b> |
| Indigenous                                      | 1 (1.4)                  | 0 (0.0)         | 1 (0.2)                    | 1 (0.2)          |
| South Asian                                     | 1 (1.4)                  | 0 (0.0)         | 2 (0.3)                    | 6 (0.9)          |
| East Asian                                      | 1 (1.4)                  | 1 (1.5)         | 6 (0.9)                    | 6 (0.9)          |
| Hispanic/Latino                                 | 0 (0.0)                  | 1 (1.5)         | 7 (1.1)                    | 5 (0.8)          |
| White   | 69 (94.5)                | 63 (91.2)       | 614 (95.2)                 | 621 (95.2)       |
| Black   | 1 (1.4)                  | 3 (4.3)         | 11 (1.7)                   | 12 (1.8)         |
| Middle Eastern                                  | 0 (0.0)                  | 1 (1.5)         | 2 (0.3)                    | 1 (0.2)          |
| <b>BMI, n (%)</b>                               | <b>(n = 72)</b>          | <b>(n = 69)</b> | <b>(n = 625)</b>           | <b>(n = 636)</b> |
| Underweight (< 18.5 kg/m <sup>2</sup> )         | 0 (0.0)                  | 2 (2.9)         | 35 (5.6)                   | 36 (5.7)         |
| Normal weight (18.5 to 24.9 kg/m <sup>2</sup> ) | 41 (57.0)                | 32 (46.4)       | 316 (50.6)                 | 304 (47.8)       |
| Overweight (25 to 29.9 kg/m <sup>2</sup> )      | 24 (33.3)                | 24 (34.8)       | 193 (30.9)                 | 219 (34.4)       |
| Obese (30 to 39.9 kg/m <sup>2</sup> )           | 5 (6.9)                  | 10 (14.5)       | 72 (11.5)                  | 73 (11.5)        |
| Morbidly obese (≥ 40 kg/m <sup>2</sup> )        | 2 (2.8)                  | 1 (1.4)         | 9 (1.4)                    | 4 (0.6)          |
| <b>Prefracture living status, n (%)</b>         |                          |                 |                            |                  |
| Institutionalized                               | 0 (0.0)                  | 0 (0.0)         | 30 (4.7)                   | 27 (4.1)         |
| Not institutionalized                           | 73 (100.0)               | 70 (100.0)      | 615 (95.3)                 | 626 (95.9)       |
| <b>Prefracture functional status, n (%)</b>     |                          |                 |                            |                  |
| Use of aid                                      | 0 (0.0)                  | 0 (0.0)         | 187 (29.0)                 | 182 (27.9)       |
| Independent ambulator                           | 73 (100.0)               | 70 (100.0)      | 458 (71.0)                 | 471 (72.1)       |
| <b>ASA grade, n (%)</b>                         |                          |                 |                            |                  |
| I/II  | 73 (100.0)               | 70 (100.0)      | 261 (40.5)                 | 248 (38.0)       |
| III-V   | 0 (0.0)                  | 0 (0.0)         | 384 (59.5)                 | 405 (62.0)       |
| <b>Major comorbidities, n (%)</b>               |                          | <b>(n = 69)</b> | <b>(n = 643)</b>           |                  |
| Osteopenia                                      | 4 (5.5)                  | 7 (10.0)        | 24 (3.7)                   | 23 (3.5)         |
| Osteoporosis                                    | 6 (8.2)                  | 9 (12.9)        | 108 (16.8)                 | 101 (15.5)       |
| Lung disease                                    | 7 (9.6)                  | 11 (15.7)       | 120 (18.7)                 | 111 (17.0)       |
| Diabetes  | 11 (15.1)                | 9 (12.9)        | 124 (19.3)                 | 136 (20.8)       |
| Ulcers or stomach disease                       | 2 (2.7)                  | 4 (5.7)         | 47 (7.3)                   | 63 (9.6)         |
| Kidney disease                                  | 1 (1.4)                  | 3 (4.3)         | 70 (10.9)                  | 64 (9.8)         |
| Anaemia or other blood disease                  | 2 (2.7)                  | 2 (2.9)         | 46 (7.2)                   | 53 (8.1)         |
| Depression                                      | 4 (5.5)                  | 6 (8.6)         | 66 (10.3)                  | 78 (11.9)        |
| Cancer  | 6 (8.2)                  | 7 (10.0)        | 59 (9.2)                   | 73 (11.2)        |
| Osteoarthritis/degenerative arthritis           | 4 (5.5)                  | 4 (5.7)         | 107 (16.6)                 | 87 (13.3)        |
| Back pain                                       | 3 (4.1)                  | 5 (7.1)         | 61 (9.5)                   | 66 (10.1)        |
| Rheumatoid arthritis                            | 3 (4.1)                  | 3 (4.3)         | 10 (1.6)                   | 18 (2.8)         |
| Heart disease                                   | 9 (12.3)                 | 4 (5.7)         | 238 (37.0)                 | 245 (37.5)       |
| High blood pressure                             | 29 (39.7)                | 24 (34.3)       | 405 (63.0)                 | 419 (64.2)       |

ASA, American Society of Anesthesiologists; HA, hemiarthroplasty; SD, standard deviation; THA, total hip arthroplasty.

and medically fit for the procedure should be considered for a THA.<sup>2</sup> The AAOS guidelines from 2014 indicate that there is moderate evidence to use THA in “properly selected patients”, i.e. higher-functioning patients.<sup>3</sup> Other reviews and meta-analyses also recommend a select group of the fittest patients for THA,<sup>5,6</sup> based on a modest benefit of THA

over HA in trials published in the past 30 years. Some trials have used HA implants that are no longer recommended, and some have not reported implant details.<sup>6,7</sup>

The Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemiarthroplasty (HEALTH) trial, including 1,495 patients, is the largest randomized controlled trial (RCT)

**Table II.** Functional outcome measures by cohort.

| End point       | Fittest cohort (n = 143)   |                                     | Other patients (n = 1,298) |                                     |
|-----------------|----------------------------|-------------------------------------|----------------------------|-------------------------------------|
|                 | Observations, n (patients) | Adjusted mean difference (99% CI) * | Observations, n (patients) | Adjusted mean difference (99% CI) * |
| WOMAC Total     | 517 (104)                  | 3.96 (-3.59 to 11.51)               | 3,614 (839)                | -0.94 (-3.57 to 1.69)               |
| WOMAC Pain      | 517 (104)                  | 0.44 (-1.16 to 2.05)                | 3,614 (839)                | -0.08 (-0.59 to 0.43)               |
| WOMAC Stiffness | 517 (104)                  | 0.47 (-0.23 to 1.17)                | 3,614 (839)                | 0.09 (-0.15 to 0.33)                |
| WOMAC Function  | 517 (104)                  | 2.93 (-2.43 to 8.29)                | 3,614 (839)                | -0.88 (-2.98 to 1.14)               |
| EQ-5D Utility   | 651 (130)                  | -0.05 (-0.12 to 0.01)               | 4,455 (977)                | 0.02 (-1.05 to 4.32)                |
| EQ-5D VAS       | 651 (130)                  | 2.35 (-3.50 to 8.21)                | 4,455 (977)                | 0.70 (-1.62 to 3.03)                |
| SF-12 PCS       | 529 (105)                  | -2.53 (-6.46 to 1.40)               | 4,112 (901)                | 0.56 (-0.86 to 1.99)                |
| SF-12 MCS       | 529 (105)                  | 1.90 (-2.42 to 6.22)                | 4,112 (901)                | 0.38 (-1.11 to 1.86)                |
| End point       | Observations, n (patients) | OR (99% CI)                         | Observations, n (patients) | OR (99% CI)                         |
| TUG†            | 466 (138)                  | 0.98 (0.56 to 1.71)                 | 3,594 (1,130)              | 0.87 (0.69 to 1.11)                 |

\*HA versus THA; the mean difference was obtained from the multilevel model. For WOMAC, a negative value of the mean difference means that it favors THA. For EQ-5D and SF-12 data, a positive value favours THA.

†TUG was dichotomized as: a) > 12 seconds to complete the test, or unable to complete the test; b) ≤ 12 seconds to complete the test. The OR (HA vs THA) is for completing the test in more than 12 seconds or not being able to complete the test and was obtained from the multilevel model.

CI, confidence interval; EQ-5D, EuroQol five-dimension health index; HA, hemiarthroplasty; MCS, mental component summary; OR, odds ratio; PCS, physical component summary; SF-12, 12-Item Short Form Survey; THA, total hip arthroplasty; TUG, Timed Up and Go test; VAS, visual analogue scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

to date comparing HA and THA in fragility fracture patients who were able to walk either with or without an assistive device pre-injury.<sup>8</sup> The HEALTH trial found no difference in the primary endpoint (a secondary hip procedure) but there was a statistically significant benefit in function for THA measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).<sup>9</sup> However, the benefit in WOMAC was smaller than what was considered clinically meaningful.<sup>8</sup> The primary end point in HEALTH was also analyzed by age, prefracture living setting, prefracture functional status, and American Society of Anesthesiologists (ASA)<sup>10</sup> grade without any differences between the treatment groups. Hence, the main conclusion from the HEALTH trial was that HA and THA are equally effective.<sup>8,11</sup> An editorial accompanying the HEALTH trial in the *New England Journal of Medicine* raised the question that there may be patients who could benefit from THA.<sup>12</sup> A separate cost-effectiveness analysis based on the HEALTH trial suggested that THA was cost-effective for the youngest patients included in the trial, based on lower cost and higher health-related quality of life (HRQoL) during the two years of follow-up for patients below 73 years of age.<sup>13</sup> A meta-analysis, including HEALTH and 15 other randomized trials, concluded that there are likely no clinically important differences between THA and HA, but discussed a modest benefit for THA in function and HRQoL.<sup>11</sup> To address this controversy, we aimed to explore the functional results in a fitter subgroup of the participants in the HEALTH trial to determine whether there was an advantage to THA in this population.

## Methods

**HEALTH study overview.** The HEALTH trial included independent ambulatory participants aged over 50 years with a

displaced, low-energy FNF.<sup>14</sup> The primary outcome was need for revision surgery, while functional outcomes and HRQoL were also evaluated. The inclusion period was from January 2009 to May 2017, at 80 participating centres in ten countries. A total of 1,495 patients were randomized to either THA or HA. The participants were followed for two years. The HEALTH trial (ClinicalTrials.gov number NCT00556842) was approved by the McMaster University Research Ethics Board (#06-151) and by the research ethics boards/institutional review boards of all participating clinical sites. Further trial data have been published previously.<sup>8</sup>

**Hip function assessment.** Functional outcome and HRQoL were measured using the WOMAC questionnaire, 12-Item Short Form Survey (SF-12),<sup>15</sup> EuroQol five-dimension health index (EQ-5D),<sup>16,17</sup> and Timed Up and Go test (TUG).<sup>18</sup> The WOMAC measures pain, stiffness and physical function, with a total ranging from 0 to 96, with higher scores indicating more pain, stiffness, and functional problems. The SF-12 measures self-reported HRQoL through an eight-domain profile of functional health and wellbeing. Each domain was scored separately from 0 (lowest level of health) to 100 (highest level of health) using standardized scoring methods to calculate a norm-based physical component summary (PCS) and a mental component summary (MCS). From the five questions of the EQ-5D, we calculated the utility index score ranging from 0 (worst) to 1 (best health utility). We also used the EQ-5D visual analogue scale (VAS) ranging from 0 (worst possible health) to 100 (best possible health). The TUG test is a standardized, physical test to assess balance and mobility in participants by timing the length of time to complete simple physical movements, such as rising from an armchair, walking ten feet, walking back to the chair, and sitting down. A

**Table III.** Complications, mortality, and serious adverse events.

| Endpoint  | Fittest cohort (n = 143) |             | Other patients (n = 1,298) |              |
|---|--------------------------|-------------|----------------------------|--------------|
|   | THA (n = 73)             | HA (n = 70) | THA (n = 645)              | HA (n = 653) |
| Unplanned secondary procedure, n (%)  | 4 (5.5)                  | 6 (8.6)     | 53 (8.2)                   | 54 (8.3)     |
| <b>Components of primary end point, n (%)</b>                               |                          |             |                            |              |
| Closed reduction of hip dislocation   | 2 (2.7)                  | 1 (1.4)     | 27 (4.2)                   | 11 (1.7)     |
| Open reduction of hip dislocation   | 0 (0.0)                  | 0 (0.0)     | 4 (0.6)                    | 2 (0.3)      |
| Open reduction of fracture  | 1 (1.4)                  | 2 (2.9)     | 4 (0.6)                    | 6 (0.9)      |
| Soft-tissue procedure   | 1 (1.4)                  | 1 (1.4)     | 14 (2.2)                   | 14 (2.1)     |
| Insertion of antibiotic spacer  | 1 (1.4)                  | 2 (2.9)     | 2 (0.3)                    | 1 (0.2)      |
| Full implant exchange   | 1 (1.4)                  | 2 (2.9)     | 6 (0.9)                    | 16 (2.5)     |
| Partial implant exchange  | 2 (2.7)                  | 3 (4.3)     | 17 (2.6)                   | 15 (2.3)     |
| Reorientation of femoral component  | 0 (0.0)                  | 0 (0.0)     | 0 (0.0)                    | 2 (0.3)      |
| Reorientation of acetabular component                                       | 0 (0.0)                  | 0 (0.0)     | 2 (0.3)                    | 0 (0.0)      |
| Implant removal with no arthroplasty  | 0 (0.0)                  | 1 (1.4)     | 3 (0.5)                    | 2 (0.3)      |
| Excision heterotopic ossification   | 0 (0.0)                  | 0 (0.0)     | 0 (0.0)                    | 0 (0.0)      |
| Supplementary fixation  | 1 (1.4)                  | 0 (0.0)     | 2 (0.3)                    | 1 (0.2)      |
| Other   | 0 (0.0)                  | 2 (2.9)     | 1 (0.2)                    | 1 (0.2)      |
| <b>Secondary end points, n (%)</b>  |                          |             |                            |              |
| Mortality   | 2 (2.7)                  | 1 (1.4)     | 101 (15.7)                 | 94 (14.4)    |
| Serious adverse events  | 11 (15.1)                | 12 (17.1)   | 289 (44.8)                 | 253 (38.7)   |
| Any hip-related complication  | 14 (19.2)                | 16 (22.9)   | 118 (18.3)                 | 102 (15.6)   |
| <b>Complications, n (%)</b>   |                          |             |                            |              |
| Periprosthetic fracture   | 6 (8.2)                  | 4 (5.7)     | 32 (5.0)                   | 31 (4.7)     |
| Hip instability or dislocation  | 2 (2.7)                  | 0 (0.0)     | 32 (5.0)                   | 17 (2.6)     |
| Superficial SSI   | 1 (1.4)                  | 0 (0.0)     | 8 (1.2)                    | 6 (0.9)      |
| Deep SSI  | 1 (1.4)                  | 2 (2.9)     | 16 (2.5)                   | 14 (2.1)     |
| Another wound healing problem   | 0 (0.0)                  | 0 (0.0)     | 6 (0.9)                    | 5 (0.8)      |
| Another soft-tissue procedure   | 2 (2.7)                  | 2 (2.9)     | 9 (1.4)                    | 9 (1.4)      |
| Clinically important heterotopic ossification (Brooker grade III or higher) | 0 (0.0)                  | 0 (0.0)     | 29 (4.5)                   | 24 (3.7)     |
| Abductor failure  | 0 (0.0)                  | 1 (1.4)     | 1 (0.2)                    | 2 (0.3)      |
| Implant failure (loosening or subsidence)                                   | 0 (0.0)                  | 1 (1.4)     | 5 (0.8)                    | 4 (0.6)      |
| Implant failure (breakage)  | 0 (0.0)                  | 0 (0.0)     | 1 (0.2)                    | 0 (0.0)      |
| Pain  | 3 (4.1)                  | 2 (2.9)     | 3 (0.5)                    | 10 (1.5)     |
| Neurovascular injury (technical error)                                      | 0 (0.0)                  | 0 (0.0)     | 2 (0.3)                    | 1 (0.2)      |
| Other   | 2 (2.7)                  | 2 (2.9)     | 5 (0.8)                    | 11 (1.7)     |

HA, hemiarthroplasty; SSI, surgical site infection; THA, total hip arthroplasty.

faster time indicates that the participant has greater functional performance, while a lower score may identify participants who are at risk for increased falls in the community.

**Statistical analysis.** No subgroup analyses on functional outcomes were planned in the HEALTH trial. However, because of the statistically significant difference in WOMAC scores favoring THA in the primary HEALTH manuscript,<sup>8</sup> we believe that it was justified to explore the data further. Hence, the analyses presented here are post hoc exploratory analyses.

For the HEALTH trial, minimization was performed at randomization to achieve balanced groups. The minimization factors were age (50 to 80 years or > 80 years), prefracture living setting (living in an institution or not), prefracture functional status (able to walk without an assistive device or not), and ASA grade (I/II or III/IV). We used these minimization variables as a guide when

defining our fittest participant cohort. The fittest patients in our analysis included those aged 70 years or younger, with an ASA grade of I or II, not using assistive devices for ambulation, and living independently preinjury. For consistency, we followed the same methods used in the primary HEALTH manuscript for our analyses in terms of the type of modelling, point estimates, and significance levels selected.<sup>8</sup> Multilevel models were used to separately estimate the effect of THA as compared with HA on function (WOMAC), HRQoL (SF-12 and EQ-5D), and mobility (TUG) in the fittest subgroup. Randomized treatment and visit (entered as a categorical variable) were also included as independent variables, and we adjusted the analyses for baseline scores. A difference between the groups of more than seven points on the total WOMAC score, more than four points for the SF-12, ranging from eight to 12 points for the EQ-5D VAS, and more than

**Table IV.** Functional outcome measures by cohort (sensitivity analysis).

| End point       | Fittest subgroup (n = 328)* |                                    | Other patients (n = 1,113) |                                    |
|-----------------|-----------------------------|------------------------------------|----------------------------|------------------------------------|
|                 | Observations, n (patients)  | Adjusted mean difference (99% CI)† | Observations, n (patients) | Adjusted mean difference (99% CI)† |
| WOMAC Total     | 1,206 (248)                 | 4.48 (-0.29 to 9.25)               | 2,925 (695)                | -2.21 (-5.09, 0.68)                |
| WOMAC Pain      | 1,206 (248)                 | 0.41 (-0.56 to 1.38)               | 2,925 (695)                | -0.20 (-0.76 to 0.37)              |
| WOMAC Stiffness | 1,206 (248)                 | 0.52 (0.07 to 0.97)                | 2,925 (695)                | 0.002 (-0.26 to 0.27)              |
| WOMAC Function  | 1,206 (248)                 | 3.31 (-0.16 to 6.78)               | 2,925 (695)                | -1.87 (-4.09 to 0.35)              |
| EQ-5D Utility   | 1,489 (296)                 | -0.03 (-0.06 to 0.01)              | 3,617 (811)                | 0.02 (-0.008 to 0.05)              |
| EQ-5D VAS       | 1,489 (296)                 | -0.43 (-4.38 to 3.53)              | 3,617 (811)                | 1.61 (-0.97 to 4.18)               |
| SF-12 PCS       | 1,277 (254)                 | -2.64 (-5.37 to 0.09)              | 3,364 (752)                | 1.32 (-0.21 to 2.84)               |
| SF-12 MCS       | 1,277 (254)                 | 0.88 (-1.76 to 3.51)               | 3,364 (752)                | 0.49 (-1.16 to 2.14)               |
| Endpoint        | Observations, n (patients)  | OR (99% CI)                        | Observations, n (patients) | OR (99% CI)                        |
| TUG‡            | 1,041 (310)                 | 0.89 (0.61 to 1.29)                | 3,021 (960)                | 0.84 (0.63 to 1.11)                |

\*The fit subgroup in the sensitivity analysis consisted of patients 80 years old or below, American Society of Anesthesiologists grade I/II, ambulatory without assistive device and living in their own home prefracture.

†HA vs THA; the mean difference was obtained from the multilevel model. For WOMAC, a negative value of the mean difference means that it favours THA. For EQ-5 D and SF-12 data, a positive value favors THA.

‡TUG was dichotomized as: a) > 12 seconds to complete the test, or unable to complete the test; b) ≤ 12 seconds to complete the test. The OR (THA vs HA) is for completing the test in more than 12 seconds or not being able to complete the test and was obtained from the multilevel model.

CI, confidence interval; EQ-5D, EuroQol five-dimension health index; HA, hemiarthroplasty; MCS, mental component summary; OR, odds ratio; PCS, physical component summary; SF-12, 12-Item Short Form Survey; THA, total hip arthroplasty; TUG, Timed Up and Go test; VAS, visual analogue scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

0.074 for the EQ-5D index were considered clinically meaningful.<sup>19–22</sup> The WOMAC, SF-12, and EQ-5D were summarized using adjusted mean differences (AMD) and 99% confidence intervals (CIs). We analyzed the TUG as a dichotomous outcome with the following categories: patients who completed the test in ≤ 12 seconds, and those who required > 12 seconds to complete the test or were unable to complete the test. The timepoint of 12 seconds was used as the cut-off because this was the threshold used by the Centres for Disease Control and Prevention.<sup>23</sup> The TUG was summarized using odds ratios (ORs) and 99% CIs. We performed the same analysis on the remainder of participants who were not included as part of the fittest population. In addition, we performed a sensitivity analysis using the same minimization parameters for defining the fittest cohort, with exception of the age limit being changed to 80 years and younger. The sensitivity analysis was performed to avoid a lack of generalizability potentially arising from too narrow a patient selection in the main analysis. We were underpowered to perform similar analyses for the primary HEALTH outcome of unplanned secondary procedures but presented the descriptive statistics as frequencies and percentages. All analyses were performed using R v. 4.0.2 (R Foundation for Statistical Computing, Austria).

## Results

**Participants.** There were 143 patients who met the criteria to be included in the fittest subgroup (Table I). Of these participants, 73 were randomized to the THA group and 70 were randomized to the HA group in the

original trial. In the HA group, there were 35 bipolar HA procedures completed, 26 unipolar procedures, and nine protocol deviations where the participant underwent surgical treatment with either internal fixation or crossover to THA. In the THA group, 70 participants underwent a THA procedure and three had a crossover to HA. The mean age of participants in the fittest subgroup was 66 years (SD 4.5) and 103 were female (72%).

**Original analysis.** The differences between the THA and HA treatment groups in the fittest cohort fell below the threshold for a minimal clinically important difference (MCID) for the overall WOMAC score and its subcomponents, the SF-12, and EQ-5D scores.<sup>8</sup> The TUG scores did not differ significantly between the THA and HA groups in the fittest cohort (Table II). Similarly, in participants who were not included in the fittest cohort, no clinically important differences were found in any of the functional outcomes. There was a similar number of unplanned secondary procedures between the THA and HA groups in the fittest cohort (Table III).

**Sensitivity analysis.** The sensitivity analysis included 328 patients in the fit cohort aged 80 years old or below (Table IV). The results of the sensitivity analysis showed similar findings to the primary analysis. None of the differences in the functional outcomes between the THA and HA groups of the fit cohort crossed the threshold for a MCID.

## Discussion

Our analyses support the main results from the HEALTH trial: THA and HA produce similar clinical results, even in the fittest



patients. Hence, the results do not support previous findings of a potentially clinically relevant benefit from THA in fittest patients. This may be due to the methodological rigour of the HEALTH trial, including the expertise-based design. Additionally, the HEALTH protocol discouraged the use of non-modular and non-canal-filling unipolar implants. A bipolar HA may be advantageous in more functionally demanding patients due to less acetabular erosion and a lower revision rate compared to unipolar HA.<sup>24–26</sup> Subgroup analyses in the most recent meta-analysis published before the HEALTH trial showed that the advantage for THA in reoperations was driven by comparison with unipolar HA.<sup>6</sup> This finding may be explained by the use of older, inferior HA implants. Several of the cited papers did not report adequate information on the HA used, and one relatively large (n = 180) quasirandomized study used a non-modular, non-canal-filling unipolar uncemented HA.<sup>7</sup>

Limitations of the present analysis include a loss of statistical power by selecting a relatively small subgroup and wide 99% CIs, including clinically relevant benefits for both treatment groups. Tables II and IV show missing data for all outcome measures, with 104 to 138 patients reported in the main analysis, and 248 to 310 patients in the sensitivity analysis. However, the number of patients is comparable to most previous trials comparing THA and HA.<sup>11</sup> Moreover, while this subgroup was defined as fittest based on age, ASA grade, ambulation without aids, and living independently, this may not be the most optimal surrogate for fitness, and an even more in-depth knowledge about activity level and preferred activities would possibly have been useful. Another limitation is the follow-up of two years. Patients in the fittest subgroup have a long life expectancy. Some previous reports have indicated that the benefit of a THA versus a HA occurs after more than two years.<sup>6,27–29</sup> In the HEALTH trial, there were more revision surgeries for HA in the second year of follow-up. However, Ekhtiari et al<sup>11</sup> examined secondary surgeries up to five years in their meta-analysis, and found a similar revision rate between THA and HA (OR 0.89 (95% CI 0.66 to 1.20)).<sup>11</sup> A recent study from the Australian Orthopaedic Association National Joint Replacement Registry did not find statistically significant differences in long-term revision risk between bipolar HA and THA in patients aged 50 to 79 years after statistical adjustments.<sup>30</sup>

It may be argued that the HEALTH trial already consisted of a select group of patients. Most patients in the HEALTH trial would have been recommended for a THA according to the NICE guidelines.<sup>2</sup> Mean age was below 80 years and only 4% were institutionalized prefracture. All were independent ambulators, and three-quarters were able to walk without an assistive device. For the main analysis of the fittest patients, we selected 143 patients, about 10% of the HEALTH patients, and for the sensitivity analysis, we included 23% of the participants in the HEALTH trial.

One uncertainty that remains is if high-functioning patients who are expected to lead an active life beyond

five years post-fracture will benefit from a THA in either function or reduced revision rate. A sufficiently large RCT studying this group with long-term follow-up will potentially clarify this, but it will be difficult to perform. High-quality registry nested trials comparing modern implants, preferably with knowledge on both implant use and surgeon experience, as well as functional results, will be of use. Other study designs, including instrumental variable analysis, may find causal answers based on practice variation. Our results indicate, however, that very few, if any, patients aged over 50 years with a displaced low-energy FNF benefit in a clinically meaningful way from a THA versus a HA the first two years after their injury.



### Take home message

- No relevant clinical advantage was found with total hip arthroplasty (THA) compared to hemiarthroplasty (HA) in fit patients aged 50 to 70 years with a displaced femoral neck

fracture.

- The trial was strengthened by a minimum surgical expertise for both implants which was defined in the protocol, and surgeons were required to use modern implants, excluding non-modular non-canal-filling HAs.

- A possible advantage of THA may become apparent after more than two years.

### Twitter

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### Supplementary material

A full list of the HEALTH Investigators.



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