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SYSTEMATIC REVIEW

Follow-up definitions in clinical orthopaedic research

A SYSTEMATIC REVIEW

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Aims

The follow-up interval of a study represents an important aspect that is frequently mentioned in the title of the manuscript. Authors arbitrarily define whether the follow-up of their study is short-, mid-, or long-term. There is no clear consensus in that regard and definitions show a large range of variation. It was therefore the aim of this study to systematically identify clinical research published in high-impact orthopaedic journals in the last five years and extract follow-up information to deduce corresponding evidence-based definitions of short-, mid-, and long-term follow-up.

Methods

A systematic literature search was performed to identify papers published in the six highest ranked orthopaedic journals during the years 2015 to 2019. Follow-up intervals were analyzed. Each article was assigned to a corresponding subspecialty field: sports traumatology, knee arthroplasty and reconstruction, hip-preserving surgery, hip arthroplasty, shoulder and elbow arthroplasty, hand and wrist, foot and ankle, paediatric orthopaedics, orthopaedic trauma, spine, and tumour. Mean follow-up data were tabulated for the corresponding subspecialty fields. Comparison between means was conducted using analysis of variance.

Results

Of 16,161 published articles, 590 met the inclusion criteria. Of these, 321 were of level IV evidence, 176 level III, 53 level II, and 40 level I. Considering all included articles, a long-term study published in the included high impact journals had a mean follow-up of 151.6 months, a mid-term study of 63.5 months, and a short-term study of 30.0 months.

Conclusion

The results of this study provide evidence-based definitions for orthopaedic follow-up intervals that should provide a citable standard for the planning of clinical studies. A minimum mean follow-up of a short-term study should be 30 months (2.5 years), while a mid-term study should aim for a mean follow-up of 60 months (five years), and a long-term study should aim for a mean of 150 months (12.5 years).

Level of Evidence: Level I.

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Keywords: Long-term, Mid-term, Short-term, Study design, Clinical study, Outcome

Introduction

Clinical orthopaedic research represents the basis of evidence-based orthopaedics. The primary goal of any clinical study would be to provide an answer to a clinical question by formulating a clearly defined study design that attempts to minimize bias.[1,2] The rules of study design and level of evidence (LOE) apply to orthopaedic research in the same way they do to all fields of clinical research according to the recommendations of the Oxford Centre for Evidence-Based medicine (CEBM).[3]

Follow-up represents an important aspect of clinical orthopaedic research, given that the success of any treatment modality depends

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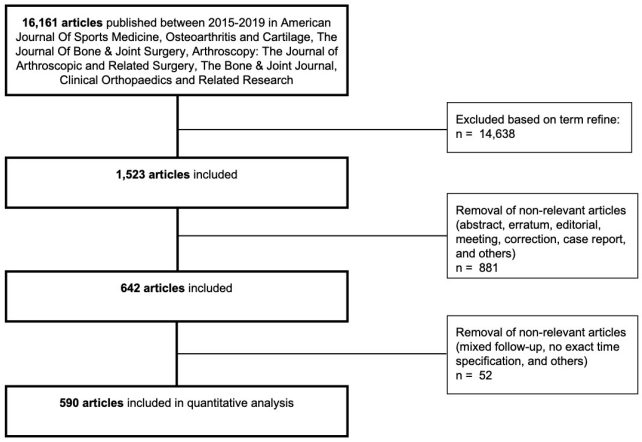

Fig. 1
Flowchart demonstrating inclusion.

Table I. Included articles from different top-ranked orthopaedic journals.

Journal	Short-term	Mid-term	Long-term
American Journal of Sports Medicine	44	57	65
Osteoarthritis and Cartilage	3	0	8
Journal of Bone and Joint Surgery	6	15	64
Clinical Orthopaedics and Related Research	41	16	66
Arthroscopy	27	26	20
The Bone & Joint Journal	25	32	75
Total	146	146	298

on the longevity of the achieved subjective and objective outcome. With this in mind, a study's follow-up interval is frequently mentioned in the title of the manuscript.

Authors arbitrarily define whether the follow-up of their study is short-, mid-, or long-term. There is no clear consensus in that regard and definitions show a large range of variation. It was therefore the aim of this study to systematically identify clinical research published in high-impact orthopaedic journals in the last five years, and extract follow-up information in order to deduce corresponding evidence-based definitions of short-, mid-, and long-term follow-up.

Methods

Search strategy. A systematic literature search was performed between March and June 2020. The journal citation report (Clariavate Analytics, USA), of the year 2020 was used to identify six of the journals within the subject category of "Orthopaedics" with the highest impact factor in the field. The following journals were selected: *American Journal of Sports Medicine*; *Osteoarthritis and Cartilage*; *The Journal of Bone & Joint Surgery*; *Arthroscopy: The Journal of Arthroscopic & Related Surgery*; *The Bone & Joint Journal*; and *Clinical Orthopaedics and Related Research*.

Table II. Included articles from different subspecialities.

Subspecialty	Short-term	Mid-term	Long-term
Shoulder and elbow arthroplasty	5	9	11
Hand and Wrist	0	0	2
Hip joint preservation surgery	9	6	10
Hip arthroplasty	13	18	49
Knee arthroplasty and reconstruction	22	20	56
Foot and ankle	4	7	9
Spine	2	2	10
Pediatrics	0	3	6
Sports medicine	70	77	98
Trauma	6	4	22
Oncology	15	0	25
Total	146	146	298

The "Web of Science" database (Clariavate Analytics) was then used to generate lists of corresponding journal publications during the years 2015 to 2019. The following keyword combination was applied to determine potentially relevant titles: ((short term) OR (long term) OR (mid term) OR (shortterm) OR (longterm) OR (midterm) OR (short-term) OR (long-term) OR (mid-term)).

All potentially relevant titles and abstracts were then screened by two epidemiologically trained researchers (SSA, LH) who excluded irrelevant articles.

Inclusion criteria were:

clinical research articles published between 2015 and 2019; an intervention-based follow-up study; and articles mentioning a short-, mid-, or long-term follow-up interval.

Exclusion criteria were:

a study with no defined follow-up interval or no stated time interval; non-clinical study regardless of type; systematic reviews and meta-analyses.

Quality assessment. Two reviewers (SSA, LH) reviewed each study individually. The study design was categorized, and a level of evidence was assigned based on CEBM recommendations. Disagreement was solved by consensus.

Data extraction. The following information was extracted: year of publication, title, follow-up interval in months, range of follow-up, and Kaplan-Meier survival estimations if available. Furthermore, each article was assigned to a corresponding subspecialty field. The following subspecialty fields were defined for that purpose: sports traumatology, knee arthroplasty and reconstruction, hip-preserving surgery, hip arthroplasty, shoulder and elbow arthroplasty, hand and wrist, foot and ankle,

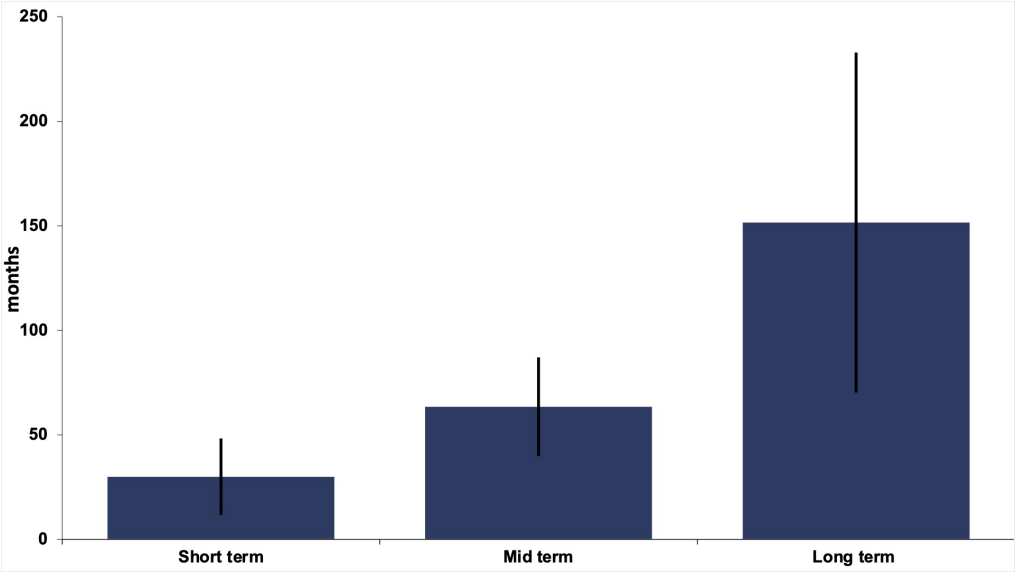

Fig. 2

Follow-up intervals stated as short-term, mid-term, or long-term in articles published in the six highest ranked orthopaedic journals between 2015 to 2019.

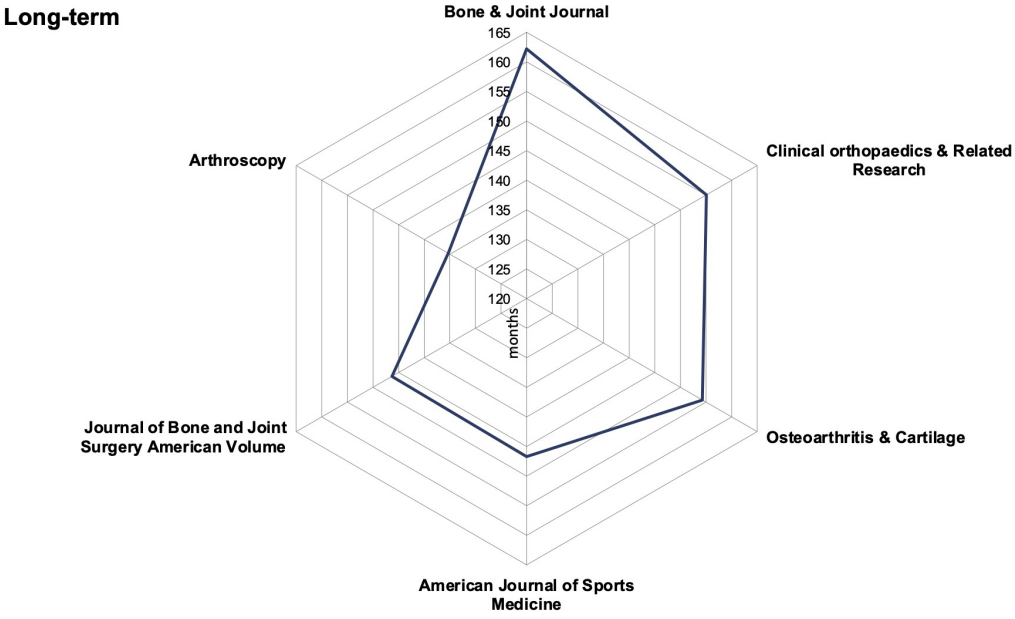

Fig. 3

Follow-up intervals defined as long-term for articles published in the six top-ranked journals in the field of orthopaedics.

paediatric orthopaedics, orthopaedic trauma, spine, and tumour.

Statistical analysis. Mean follow-up data were tabulated for the corresponding subspecialty fields. For studies reporting medians, means were calculated using the following formula:[4]

$$x = \frac{a + 2m + b}{4}$$

Where the mean (x) was calculated from the values of the median (m), and low and high ends of the range (a and b, respectively). This was not necessary for a sample size exceeding 25[4]. Comparison between means was conducted using analysis of variance (ANOVA). A p-value < 0.05 was considered statistically significant. SPSS 25 (USA) was used for statistical purposes.

Results

From a total of 16,161 published articles, 590 met the inclusion criteria and were included for further evaluation (Figure 1). Of these, 321 were of level IV evidence, 176 level III, 53 level II, and 40 level I. The number of included

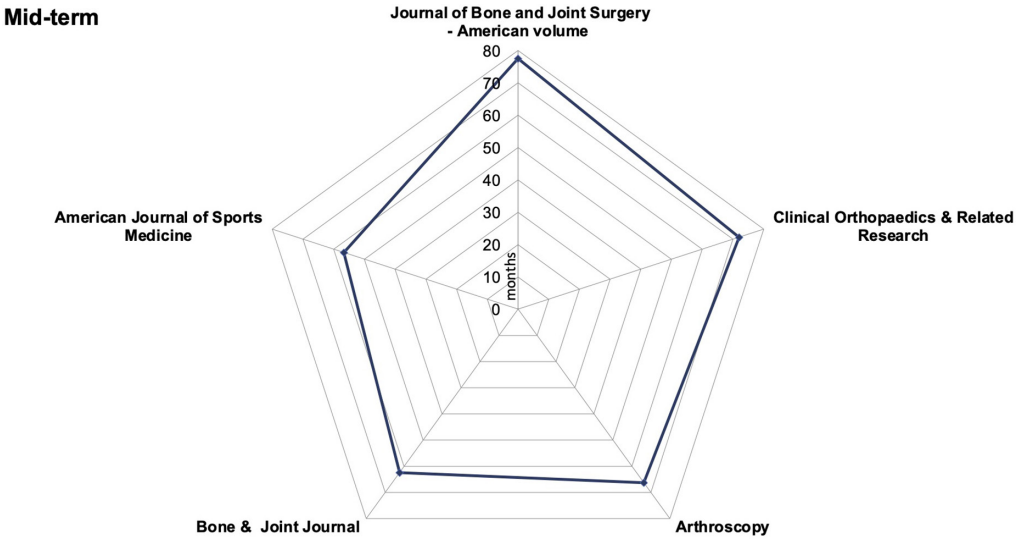

Fig. 4

Follow-up intervals defined as mid-term for articles published in the six top-ranked journals in the field of orthopaedics.

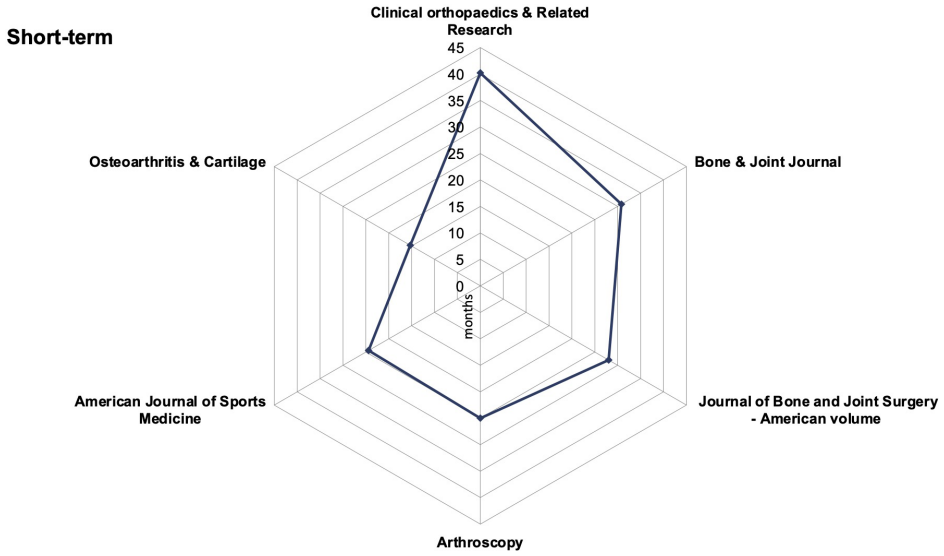

Fig. 5

Follow-up intervals defined as short-term for articles published in the six top-ranked journals in the field of orthopaedics.

articles per journal is illustrated in Table I. The number of included articles per subspecialty is illustrated in Table II.

Considering all included articles, long-term studies published in the included high-impact journals had a mean follow-up of 151.6 months, mid-term studies of 63.5 months, and short-term studies of 30.0 months (Figure 2).

Follow-up definitions by journal. The mean reported long-term follow-up intervals for studies defined as long-term studies ranged from 135 months for "Arthroscopy" to 162 months for the *The Bone & Joint Journal* (Figure 3). However, there was no significant difference between journals (p = 0.152, ANOVA). The mean reported follow-up intervals for studies defined as mid-term studies ranged from 56 months for *Am J Sports Med* to 77 months for *J Bone Joint Surg Am*. The *Am J Sports Med* has the shortest mean mid-term follow-up definition compared to *J Bone Joint Surg Am* (p = 0.077, ANOVA) and *Clin Orthop Relat Res* (p = 0.013, ANOVA) (Figure 4).

The mean reported short-term follow-up definition for articles defined as short-term studies ranged from 15 months for Osteoarthritis & Cartilage to 39 months for Clin Orthop Relat Res (p = 0.131, ANOVA) (Figure 5).

Follow-up definitions by subspecialty area. The mean reported long-term follow-up definition ranged from 116 months for hand and wrist articles to 186 months for foot and ankle articles, with no significant difference between the categories (p = 0.117, ANOVA) (Figure 6).

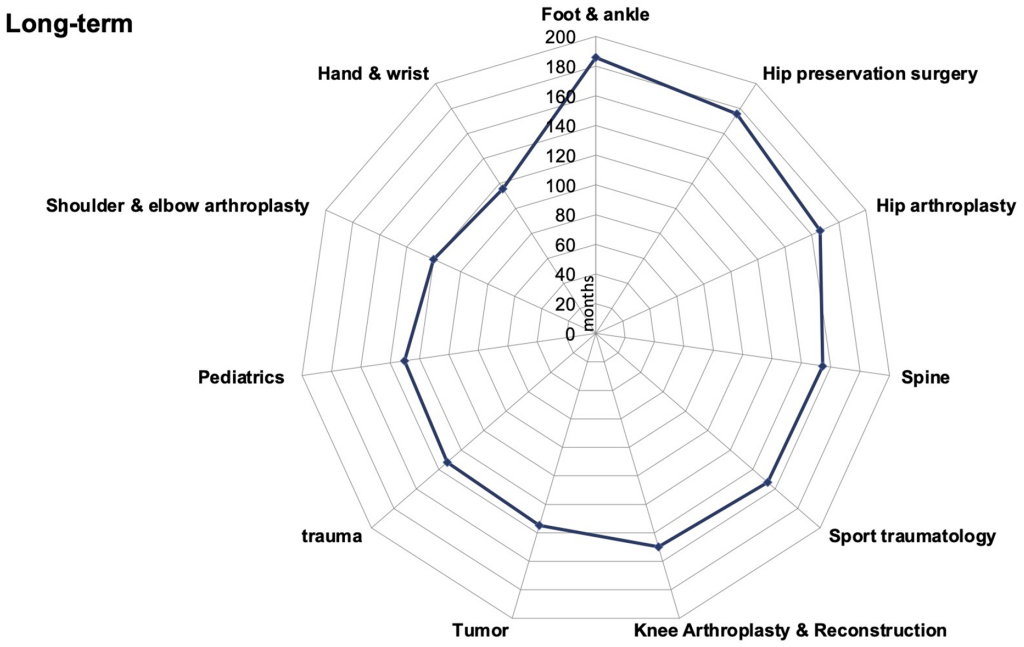

Fig. 6

Follow-up intervals defined as long-term for different orthopaedic subspecialties.

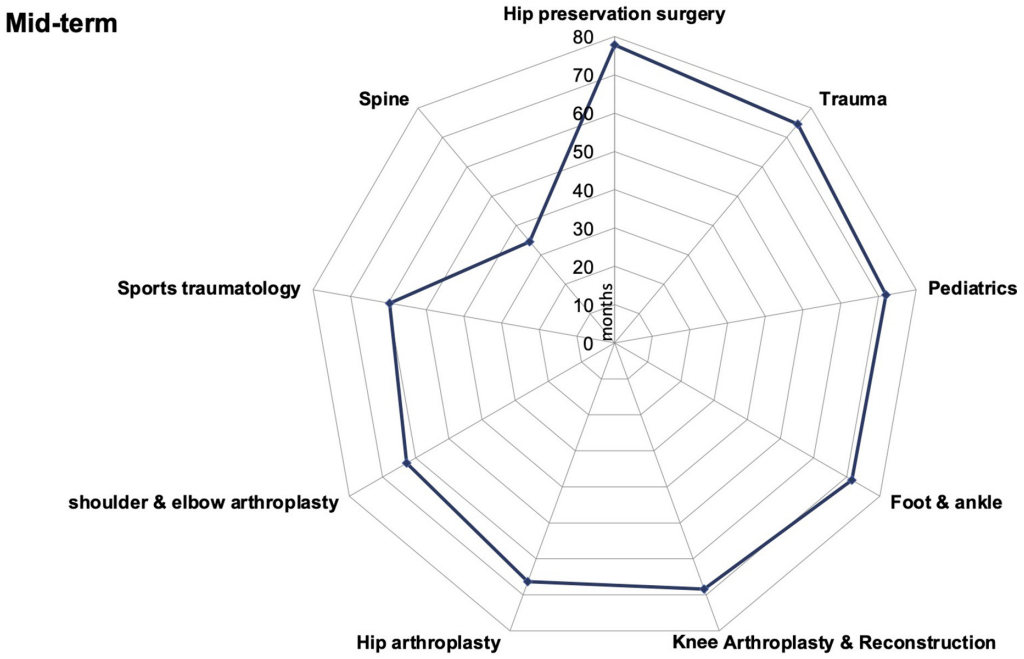

Fig. 7

Follow-up intervals defined as mid-term for different orthopaedic subspecialties.

The mean reported mid-term follow-up definition ranged from 34.5 months for spine surgery to 78 months for the field of hip preservation surgery (Figure 7).

The mean reported short-term follow-up definition ranged from 11 months for trauma to 50 months for hip arthroplasty ($p < 0.001$). The shortest follow-up was for the three categories trauma, spine, and sports traumatology. The longest follow-up was for both hip arthroplasty and hip preservation surgery (Figure 8).

Discussion

The findings of this study elucidate follow-up interval definitions that are agreed upon by the orthopaedic community. It is of upmost importance during the

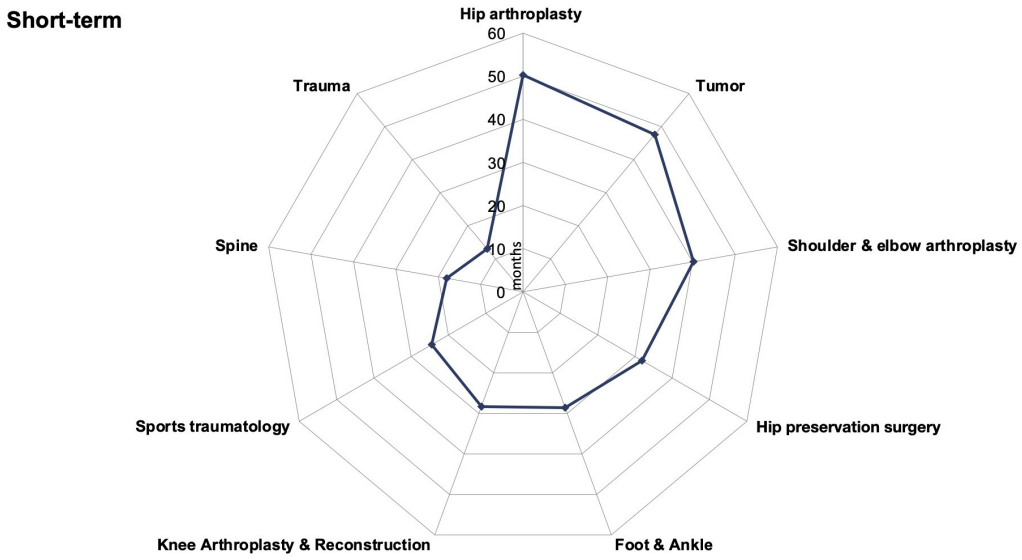

Fig. 8

Follow-up intervals defined as short-term for different orthopaedic subspecialties.

formulation of a clinical study design to identify a suitable postoperative follow-up interval in order to capture the defined outcome measures. This varies based on the corresponding primary research question of the study.

In the field of surgical oncology, the primary outcome measure is survival of the patient. Here, survival of five years or more is commonly referred to as long-term survival and subsequently, the study would deemed long-term.[5,6] The case is different in clinical orthopaedic research, where survival of the implant and patient satisfaction represent determining factors and require longer monitoring. The rather long required follow-up in orthopaedic research reflects the fact that the success of treatment cannot be confined to the initial postoperative years.[7-10] Nevertheless, it is important to publish the early- and mid-term reports of a clinical study to allow for early distribution of results.

It is important to emphasize that published clinical research shows a wide range of disagreement regarding what is referred to as mid-term follow-up. Some authors have defined it as six months, while others have defined it as a minimum of five years.[11,12] It is therefore fair to state that the lack of a consensus regarding the definition of follow-up intervals should not be accepted in the academic orthopaedic community. Therefore, the most important implication of the findings of the current study is the provision of evidence-based definitions for follow-up intervals in orthopaedic research. This should allow for a citable standard when planning and designing a clinical study. Therefore, the minimum mean follow-up that a short-termed study should aim for is 30 months (2.5 years), while a mid-term study should aim for a mean follow-up of 60 months (five years), and a long-term study should aim for a mean of 150 months (12.5 years). An even stricter approach would be to take the aforementioned intervals (2.5, five, and 12.5 years) not as the mean but as the minimal follow-up necessary to classify a certain study as either a short-, mid-, or long-term follow-up study.

There were only moderate differences between subareas and journals regarding the duration of mean follow-up intervals, allowing the above-mentioned time periods to be generalized. However, the practice of reporting varies slightly between subspecialties. The longest follow-up intervals in studies which the authors classified as short-term can be found in hip arthroplasty, whereas the shortest interval is found in trauma (Figure 8). This ranking is different when reporting mid-term or long-term clinical studies (Figures 6 and 7). The longest long-term follow-up period can be found in the speciality of Foot and Ankle Surgery, demonstrating high scientific quality for this speciality with regards to reporting long-term clinical studies.

One limitation of this study is that, owing to the enormous data pool, the work did not grasp the entire orthopaedic literature. The authors mitigated this by restricting the review to top-ranked journals and articles published in the last five years.

To conclude, the results of this study provide evidence-based definitions for orthopaedic follow-up intervals that should offer a citable standard for the planing and design of clinical studies. A minimum mean follow-up of a short-term study should be 30 months (2.5 years), while a mid-term study should aim for a mean follow-up of 60 months (five years), and a long-term study should aim for a mean of 150 months (12.5 years) of follow-up.

Take home message

- The mean follow-up of a short-term study should be at least 30 months (2.5 years).
- The mean follow-up of a mid-term study should be at least 60 months (five years).
- The mean follow-up of a long-term study should be at least 150 months (12.5 years).

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Author contributions:

- S. S. Ahmad: Planned the study, Collected and analyzed the data, Wrote the manuscript.
- L. Hoos: Collected and analyzed the data.
- C. Perka: Supervised the study.
- U. Stöckle: Supervised the study.
- C. Konrads: Planned the study, Analyzed the data, Wrote and revised the manuscript.
- K. F. Braun: Planned the study, Revised the manuscript.

- C. Konrads and K. F. Braun contributed equally to this work.

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