

Is a Revision a Revision? An Analysis of National Arthroplasty Registries' Definitions of Revision

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Abstract

Background The reported survival of implants depends on the definition used for the endpoint, usually revision. When screening through registry reports from different countries, it appears that revision is defined quite differently.

Questions/purposes The purposes of this study were to compare the definitions of revision among registry reports and to apply common clinical scenarios to these definitions.

Methods We downloaded or requested reports of all available national joint registries. Of the 23 registries we identified, 13 had published reports that were available in English and were beyond the pilot phase. We searched these registries' reports for the definitions of the endpoint, mostly revision. We then applied the following scenarios to the definition of revision and analyzed if those scenarios were regarded as a revision: (A) wound revision without any addition or removal of implant components (such as hematoma evacuation); (B) exchange of head and/or liner (like for infection); (C) isolated secondary patella resurfacing; and (D) secondary patella resurfacing with a routine liner exchange.

Results All registries looked separately at the characteristic of primary implantation without a revision and 11 of 13 registers reported on the characteristics of revisions.

Regarding the definition of revision, there were considerable differences across the reports. In 11 of 13 reports, the primary outcome was revision of the implant. In one registry the primary endpoint was "reintervention/revision" while another registry reported separately on "failure" and "reoperations". In three registries, the definition of the outcome was not provided, however in one report a results list gave an indication for the definition of the outcome. Wound revision without any addition or removal of implant components (scenario A) was considered a revision in three of nine reports that provided a clear definition on this question, whereas two others did not provide enough information to allow this determination. Exchange of the head and/or liner (like for infection; scenario B) was considered a revision in 11 of 11; isolated secondary patella resurfacing (scenario C) in six of eight; and secondary patella resurfacing with routine liner exchange (scenario D) was considered a revision in nine of nine reports.

Conclusions Revision, which is the most common main endpoint used by arthroplasty registries, is not universally defined. This implies that some reoperations that are considered a revision in one registry are not considered a revision in another registry. Therefore, comparisons of implant performance using data from different registries have to be performed with caution. We suggest that registries work to harmonize their definitions of revision to help facilitate comparisons of results across the world's arthroplasty registries.

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Introduction

Osteoarthritis affects nearly 27 million Americans [10] and is the leading cause of long-term disability [8, 13]. Total joint arthroplasty (TJA) is an effective alternative to

medical management for the relief of pain in patients with osteoarthritis of the hip and knee [3, 19]. With an annual one million hip and knee arthroplasties performed in the United States [2], 400,000 in Germany [1], and 165,000 in the United Kingdom [16], TJA ranks among the most common high-cost procedures [21]. As a result of the success of these procedures, the *British Medical Journal* has termed TKA as the “joint of the decade” [14] and *The Lancet* has termed THA as the “operation of the century” [11].

However, TJA revisions are common. In the United States, for example, it has been reported that the revision burden is 17.5% after THA [9]. In Germany, as another example, there are an annual 160,000 primary THAs and 25,800 revisions [1], resulting in a burden of revision [9] of 14%. Revisions are an important problem both for society and for the individual patient. Several countries became aware of this problem and, as a consequence, have implemented national arthroplasty registries. The very first arthroplasty registry was started in Sweden in 1975 for registering knee arthroplasties and was followed by a hip arthroplasty registry, again in Sweden in 1979. After the implementation of these registries, the probability of revision was cut in half [6, 7, 12].

Encouraged by these experiences, several other countries started national joint registries such as Finland in 1980, Norway in 1987, Denmark in 1995, New Zealand in 1998, and Australia in 1999. After the disaster with the 3M Capital Hip system (St Paul, MN, USA), which was associated with a much higher than expected revision rate, England and Wales also implemented a national arthroplasty registry in 2003. All these national arthroplasty registries aim to report the survival of implants used for hip and/or knee arthroplasty to minimize the revision rate.

Given the high burden of revision in Germany, the national German Arthroplasty Registry was founded in 2011. When setting up the German registry, we sought to ensure high comparability to existing registries, including the definition of revision, which is the endpoint of all registries, for use in the German registry. However, when we looked at the definitions of revision in the reports of different national registries, it became evident that the definitions are quite different from one another.

Therefore we aimed to (1) compare the definition of revision in different reports; and to (2) apply different common clinical scenarios to these definitions to determine whether the different definitions might influence the likelihood that a particular procedure would be reported as a revision across the world’s registries.

Materials and Methods

Based on a Google search, the web site of the European Arthroplasty Register (EAR) (<http://www.ear.efort.org/registers.aspx>), and a Health Technology Assessment Report [4], we identified all available national joint arthroplasty registries in May 2012. Overall we could identify 23 registries, of which 13 had published reports that were available in English and were beyond the pilot phase. We downloaded the most current report from each of those registries in English to identify each registry’s definition of revision. If no such report was available on the web site of the register, we sent a written request.

A total of 13 reports could be obtained in English. Of these there were 11 reports covering knee and 11 covering hip arthroplasties (Table 1). Of the 13, a total of 11

Table 1. List of the registry reports analyzed for this study

| Registry | Date of report | THA | TKA |
|--|----------------|-----|-----|
| Australian Orthopaedic Association National Joint Replacement Registry | 2011 | ✓ | ✓ |
| Canadian Joint Replacement Register | 2008–2009 | ✓ | ✓ |
| Danish Knee Arthroplasty Register | 2010 | | ✓ |
| SoFCOT Total Hip Arthroplasty Register (France) | 2011 | ✓ | |
| National Joint Registry for England and Wales | 2011 | ✓ | ✓ |
| New Zealand Joint Register | 1999–2010 | ✓ | ✓ |
| Norwegian Arthroplasty Register | 2010 | ✓ | ✓ |
| Portuguese National Arthroplasty Register | 2010 | ✓ | ✓ |
| Registro dell’implantologia Protesica Ortopedica (Italy) | 2010 | ✓ | ✓ |
| Scottish Arthroplasty Project | 2010 | ✓ | ✓ |
| Slovakian National Arthroplasty Register | 2010 | ✓ | ✓ |
| Swedish Knee Arthroplasty Register | 2011 | | ✓ |
| Swedish Hip Arthroplasty Register | 2010 | ✓ | |
| Total | | 11 | 11 |

provided definitions on two or more of our four scenarios, and so these 11 reports represented our study group (Table 2).

Two of us (TRL, FS) then separately applied four possible clinical scenarios to the definitions of revisions identified in the reports; discrepancies between our two observers were resolved by consensus. The four scenarios were: (A) wound revision without addition or removal of implant components such as hematoma evacuation; (B) exchange of the head and/or liner, e.g., for infection; (C) isolated secondary patella resurfacing; and (D) secondary patella resurfacing with routine (prophylactic) liner exchange. The rationale for scenario D is that in some countries with large arthroplasty registers, many patients do not undergo patella resurfacing during the index procedure, and it is common that during secondary patella resurfacing, a “prophylactic” liner exchange might be done, because the liner is the component that is most susceptible to wear. Of the 13 reports, nine, 11, eight, and nine provided definitions that answered questions A through D, respectively.

Results

Comparing Registries' Definitions

All registries looked separately at the characteristics of (not revised) primary implantation, however only 11 of 13 registers reported on the characteristics of revisions. There were considerable differences across the reports. In 11 of 13 reports, the primary outcome was revision of the implant. In one registry the primary endpoint was “reintervention/revision” while another registry reported separately on “failure” and “reoperations”. In three registries, the definition of the endpoint was not provided, but in one registry a results list gave an indication for the definition of the endpoint (Table 2). If provided, there were considerable differences in the definition of the endpoint (Table 2).

Applying Clinical Scenarios

Wound revision without any addition or removal of implant components (scenario A) was considered a revision in three of nine reports that provided a clear definition on this question and two others did not provide enough information to allow this determination; exchange of head and/or liner, e.g., for infection (scenario B), was considered a revision in 11 of 11; isolated secondary patella resurfacing (scenario C) in six of eight; and secondary patella resurfacing with routine liner exchange (scenario D) was considered a revision in nine of nine reports (Table 3).

Discussion

The revision rates reported in national arthroplasty registries have a major impact on the care of patients and are important not only for surgeons, but also for implant manufacturers, healthcare decision-makers, healthcare insurance, and policymakers. Therefore, it is important that revision, which is the usual endpoint in arthroplasty registers, be universally defined so that the results of different registries are comparable. However, when we analyzed the definition of revision used in registries, it became apparent that revision is defined quite differently. Interestingly enough, there were even different definitions of revision used in registries within the same country (Swedish Hip versus Swedish Knee Registry; Norwegian Arthroplasty versus Norwegian Hip Fracture Registry, although the Norwegian Fracture Registry, because it is not an arthroplasty register, was not part of this analysis). This implies that some surgeries that are considered a revision in one registry are not considered a revision in another registry. For this reason, comparisons between different arthroplasty registries are difficult to conduct and pooling results from different registries [17] also needs to be performed with caution.

This study had a number of limitations. First, of the 23 registers that we could identify, we only obtained 13 reports in English for analysis. However, these 13 reports cover the largest and the longest established joint registries in the world such as England and Wales, most Scandinavian countries, Australia, and New Zealand to name a few. The registries not covered in our analysis are probably smaller or have not been established for a long time. Because it also appears likely that the publication of a report in English will increase its citation frequency, it could be argued that the reports not analyzed here are less influential. Moreover, it appears unlikely that the registries not analyzed here would have an identical definition of revision. Second, it is possible that we failed to find the definitions of the endpoints of interest in the registries' reports or that the definitions are documented somewhere outside the report. However, we also searched the web site of registers in which we could not find the definitions without finding a clear definition that would be able to allow the classification of our predefined scenarios. Third, we acknowledge that some registries may have difficulties assessing every reoperation in every patient and that the definition of the endpoint is adapted to the national organization of the register. For example, in paper form-based registries, it appears comprehensible that only exchanges or additions of implant components are considered a revision, because the registration is based on the implant level and therefore the registry gets a form for every component that has been implanted. In these situations, registries might not

Table 2. Definition of the endpoints in arthroplasty registers

| Register | Definition | Comment | Link |
|---|---|--|---|
| Australian Orthopaedic Association, National Joint Replacement Registry | Revision: any subsequent procedure that involves the insertion, removal, and/or replacement of a prosthesis or implant. Revision hips are reoperations of previous hip replacements where one or more of the prosthetic components are replaced, removed, or another component is added. Revisions include reoperations of primary partial, primary total, or previous revision procedures. Revision knees are reoperations of previous knee replacements where one or more of the prosthetic components are replaced, removed, or another component is added. Revisions include reoperations of primary partial, primary total, or previous revision procedures. | The scenario of wound revision without any addition or removal of implant components is not defined. Therefore, it is not clear if it is considered a revision. It does not fulfill the definition of revision, when considered "as any subsequent procedure that involves the insertion, removal and/ or replacement of a prosthesis or implant." However, it fulfills the definition "include reoperations of primary partial, primary total or previous revision procedures." | https://aoanjrr.dmac.adelaide.edu.au/documents/10180/44800/Annual%20Report%202011?version=1.2&t=1347337258367 |
| Canadian Joint Replacement Registry | Revisions are modifications or replacements made to an existing hip or knee artificial joint prosthesis/component. A revision procedure may be necessary when an existing old or worn-out hip or knee component needs to be removed and replaced with a new or improved prosthesis. This may include the removal of one or more hip or knee components as necessary. | Both the scenarios of wound revision without any addition or removal of implant components and the scenario of isolated secondary patella resurfacing are not clearly defined. In addition, the Canadian registry has not specifically addressed the issue of exchanging components in septic situations. The registry talks about "old or worn-out" components, which would not be the case in case of an (early) infection. | https://secure.cihi.ca/free_products/2008_cjrr_annual_report_en.pdf |
| Danish Knee Arthroplasty Register | A revision procedure is any subsequent operation, where the entire implant or part thereof is exchanged or removed or another component inserted to the same knee. | | https://www.knee.dk/download.php?P1=0&P2=2&P3=0&P4=2280 |

Table 2. continued

| Register | Definition | Comment | Link |
|---|---|--|---|
| England and Wales: National Joint Registry for England and Wales | <p>Revision: operation performed to remove (and usually replace) one or more components of a total joint prosthesis for whatever reason.</p> <p>Note: where no implants are removed and a patella button is implanted, this would be recorded as a single-stage revision.</p> <p>Some of the HES/PEDW defined extra revisions were found not to be revisions (involving the removal and replacement of one or more components of a total joint prosthesis) but re-operations (such as wound exploration, debridement for infection, evacuation of a hematoma, or open reduction of dislocation).</p> <p>However, without knowing about the volume of re-operations relative to the volume of revisions, it is difficult to estimate what impact this may have on revision rates calculated using HES/PEDW data.</p> | | http://www.njrcentre.org.uk/NjrCentre/Portals/0/Documents/NJR%208th%20Annual%20Report%202011.pdf |
| France: SoFCOT Total Hip Arthroplasty Register (Société Française de Chirurgie Orthopédique et Traumatologique) | <p>No definitions are provided.</p> | <p>The endpoint is “reintervention/revision.” No definitions are provided. However, specific operations that are considered reinterventions/revisions in the registry (including lavage) are listed in tables.</p> | http://www.google.de/url?sa=t&rc=1&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CCYQFjAA&url=http%3A%2Fwww.sofcot.fr%2Fcontent%2Fdownload%2F8277%2F50218%2Ffile%2FTHASoFCOT2013report.pdf&ei=_rLbVK7IDpPaP-ogZAE&usq=AFQJCNQ_QmA4g3FcplYCBuUNfpRepvUP3A |
| Italy: Regional Register of Orthopedic Prosthetic Implantology | <p>The prosthesis is considered to be “surviving” up to when it was necessary to intervene surgically to replace even a single component. The revision is, thus, the endpoint.</p> <p>In these analyses, patella resurfacing after primary TKA is not considered a failure. As requested by the Board, bicompartmental TKA has been calculated also considering patella resurfacing a failure (additional survival plot on page 103).</p> <p>The revision of a single component (even insert) is considered a failure.</p> <p>Prosthetization of patella, in a second surgery, is not considered a failure.</p> | | https://ripo.cineca.it/pdf/report_2010_en.pdf |

Table 2. continued

| Register | Definition | Comment | Link |
|---|---|--|---|
| New Zealand Orthopaedic Association: The New Zealand Joint Registry | Revision is defined by the Registry as a new operation in a previously replaced hip during which one of the components are exchanged, removed, manipulated, or added. It includes excision arthroplasty and amputation, but not soft tissue procedures. A two-stage procedure is registered as one revision. | | http://nzooa.org.nz/system/files/NJR%2012%20Year%20Report%20Jan%2009%20-%20Dec%202010.pdf |
| Norway: The Norwegian Arthroplasty Register | Revisions: exchange or removal of the total prosthesis or components. Types of revision: exchange, removal, Girdlestone, insertion after Girdlestone, other, missing information. | Although secondary patella resurfacing is not covered by the definition of revision, it is nevertheless listed as a revision type. In addition, there are high percentages of “other” revision types (24% after TKA with patella and 13% after TKA without patella). However, “other” is not defined. Because all procedures involving a revision of an implant are listed as separate options, it could be speculated that soft tissue surgery is also included in the “other” category, although it is not included by the definition. | http://nrlweb.ihelse.net/eng/Report_2010.pdf |
| Norway: The Norwegian Hip Fracture Register | Reoperations resulting from soft tissue revisions for infection and closed or open reduction of dislocated hemiprostheses should also be reported. This is different from the reporting to the Hip and Knee Arthroplasty Register where only reoperations with removal or changing of the implant should be reported. | The term “reoperation” is only used in the hip fracture register, but not in the arthroplasty register. | http://nrlweb.ihelse.net/eng/Report_2010.pdf |
| Portuguese Arthroplasty Register | There is no definition of the endpoint (revision and reoperations) in the report. | No clear definition of revisions. Used are the terms revision and reoperations. | www.rpa-spot.pt/Quick-Links/Home/RPA_first_anual_report.aspx |
| Scottish Arthroplasty Project | There is no definition of revision in the report. | The web site states in the glossary: “Revision surgery: When an artificial joint fails, a second operation is required to replace the failing joint. This procedure is called a revision.” There are no procedures listed that were done during revision surgery. | http://www.arthro.scot.nhs.uk/Reports/Scottish_Arthroplasty_Project_Report_2010.pdf |
| Slovakian Arthroplasty Register | A revision procedure is defined as any operation replacing any component. Revision surgery of soft tissue—any surgery after the primary implantation where only soft tissues are revised. In revision TKA the implants and their components are considered—this additionally includes the soft tissues, hence the use of the wider term “elements.” | Soft tissue revision is listed in the results section of TKA revision, but not in the results section of THA revision. Isolated secondary patella resurfacing is not covered by the definition. | http://www.sar.mfn.sk/file/subory/SAR_2010_EN.pdf |

Table 2. continued

| Register | Definition | Comment | Link |
|------------------------------------|---|--|--|
| Swedish Hip Arthroplasty Register | <p>Short-term complications, that is, reoperations (of all types) within 2 years of the primary operation. ... This variable in this connection should be considered as a "rapid" quality indicator. Note that the report applies to complications dealt with surgically. Ten-year survival of total arthroplasties according to traditional Kaplan-Meier statistics. The definition of failure is exchange of one or both components, or definitive removal of the implant. ... This variable should be considered "slow" but in the long term is an important quality indicator. Reoperations: possible items are: extraction of hemi- or total implant, open exploration of hip joint, open reposition of dislocated implant, suture/reinsertion of tendon muscle insertion, incision/débridement septic arthritis, implant medication, septic arthritis, open mobilization of joint</p> | <p>Revision appears to include all kinds of surgery in which the total implant or parts of it are revised. However, the extraction (ie, Girdlestone) is considered a reoperation and falls in the same category as suture/reinsertion of tendon muscle insertion or open reposition of dislocated implant. It is not clear from the report as to how "revision arthroplasty, other revision" is defined. Because "total revision," "cup revision," "stem revision," and "other component" are separate categories, it is unclear as to which "other revision surgeries" are not covered, apart from soft tissue surgery.</p> | <p>http://www.shpr.se/Libraries/Documents/AnnualReport-2010-2-eng.sfb.ashx</p> |
| Swedish Knee Arthroplasty Register | <p>Revision is defined as a new operation in a previously resurfaced knee during which one or more of the components are exchanged, removed, or added (including arthrodesis or amputation). This implies that soft tissue operations such as arthroscopy and lateral release are not considered revisions. The reason for this stringent definition is that some minor operations are not necessarily related to the primary surgery and thus cannot be considered a complication or failure.</p> | | <p>http://www.myknee.se/pdf/115_SKAR2011_Engl.0.pdf</p> |

Table 3. Scenarios that are considered a revision, listed separately by register

| Registry | Endpoint used for survival analysis in report | Definition of endpoint provided in report | Wound revision without any addition or removal of implant components | Exchange of head and/or liner (eg, for infection) | Isolated secondary patella resurfacing | Secondary patella resurfacing with routine inlay exchange |
|--|---|---|--|---|--|---|
| Australia | Revision | | Unclear | Yes | Yes | Yes |
| Canada | Revision (however, no survival analysis included in report so far) | Yes | Unclear | Yes | Unclear | Yes |
| Denmark | Revision | Yes | No | Yes | Yes | Yes |
| England and Wales | Revision (“we have moved from revisions [and possible reoperations] to revisions alone”) | Yes | No | Yes | Yes | Yes |
| France | “Reintervention/revision” | No, but procedures counted as “reintervention/revision” listed in results section | Yes | Yes | No applicable (hip register) | No applicable (hip register) |
| Italy | Revision | Yes | No | Yes | No | Yes |
| New Zealand | Revision | Yes | No | Yes | Yes | Yes |
| Norway | Revision | Yes | No | Yes | Yes | Yes |
| Portugal | No survival analysis yet | No | | | | |
| Scotland | Revision | No | | | | |
| Slovakia | Revision | Yes | Yes (but only for TKA) | Yes | No | Yes |
| Sweden Hip | Two endpoints: 1. Failure (exchange of one or both components, or definitive removal of the implant) 2. Short-term complications (reoperations of all types within two years of the primary operation) | Yes | Yes (for reoperation, but “no” for failure) | Yes | Not applicable (hip register) | Not applicable (hip register) |
| Sweden Knee | Revision | Yes | No | Yes | Yes | Yes |
| Number of registers in which scenario is considered a revision | | | 3 of 9 | 11 of 11 | 6 of 8 | 9 of 9 |

be aware of other reoperations in which no implant component was added or exchanged. This situation has been acknowledged by the Swedish Knee Arthroplasty Registry, in which “it was noted early on that many surgeons did not report reoperations which they did not consider directly related to the prior knee arthroplasty” [22].

The definitions of what constitutes a revision procedure varied widely across the registries we surveyed. We are not aware of any other studies that have addressed this issue before. The sparse literature touching this topic deals with the collaboration of several Scandinavian registers [5] or a comparison of the Norwegian Knee Arthroplasty Register and a US Arthroplasty Register [18]. Given the different definitions of revisions, the question arises as to what definition is the “best” or “correct” one. To answer that question, it depends on whether a revision is viewed from the patient’s or the implant’s perspective: From the patient’s perspective, any additional surgery is a burden. Therefore, it is easy to understand that secondary resurfacing of the patella could be considered a revision. If this argument is followed further, however, other wound revisions such as lavage or hematoma evacuations should be considered revisions as well, even when the implants are not touched. However, these scenarios are considered a revision in only three of nine reports. Viewed from the implant’s perspective, the question arises if an implant should be counted as a failure if it remains *in vivo* while other components such as in secondary patella resurfacing are added. Counting such implants as a failure could dilute the effect of otherwise underperforming implants in comparative analysis, resulting in the delay of the identification of underperformers.

Because there is no definite answer as how to deal with this problem up to this time, registries have developed different strategies. For example, one registry has decided to publish additional tables in which exchange of liner (for infection) are not considered as revisions [22]. Another registry changed its reference for reporting: “In early reports we looked at survivorship in terms of revision and/or reoperation.[...] ..., so the key message is that we have moved from revisions (and possible re-operations) to revisions alone. [...] This allows us to exclude revision for infection from the analysis so we are able to comment on revision for aseptic loosening which may be more pertinent in terms of assessing implants rather than other environmental and surgical factors” [15]. In their 2013 report of the Swedish Knee Arthroplasty Register, the authors discuss their strict definition of revision. They mention that different types of soft tissue surgeries were never reported by some surgeons and therefore the register has decided to use a stricter definition “which surely had to do with the implant” [22]. They also mention that in up to 20% of all revisions for

infection, the liner is exchanged, which results in these cases being counted as a revision. They address the additional problem of fixed liners (such as in all-polyethylene tibial components): if the surgeon chooses to not exchange the fixed liner, this will favor the implant in the registry report. If, on the other hand, the surgeon chose an exchange, this would “result in a reversed bias if the exchange of an inlay is not considered as being a revision” [22]. Therefore, it appears favorable that all reoperations could be captured by the registry, regardless of whether an implant component was touched. This would allow a definition of revision, which is detached from pragmatic reasons.

Applying some common clinical scenarios to the definitions of the worlds registers, we found large discrepancies in terms of whether each of those scenarios would be considered a revision among the registries we surveyed. The question arises if the different definitions used in the registries results in just a theoretical change of reported revision rate or if there is indeed a measurable change in the actual revision rate. In this respect, the authors of the most recent Swedish Knee Arthroplasty Report have performed separate analyses in which isolated exchanges of liners because of infection (scenario B of our study) were not counted as revisions [23]. They found that doing so does “affect the results and that the effect negatively affects the results of non-modular implants when compared to modular ones” [23]. The Italian registry does not consider isolated secondary patellar resurfacing to be a revision procedure (our scenario C); however, the authors of that registry have provided additional analyses in which they tallied those procedures as failures. In that reanalysis, the reported survival at 10 years decreased from 94.2% to 93.3% [20].

Because there are striking differences in the definition of revision in arthroplasty reports, we suggest that arthroplasty registries agree to standardize the definition of revisions. Once consent on this harmonization process has been achieved, we suggest that it be introduced step by step. To maintain comparability with previous reports of the same registry, it appears necessary that parts of the reports are prepared using the previously used definition of revision for the register, whereas other parts of the reports are prepared using the standardized definition of revision. Until or unless such consistency has been achieved, we suggest grouping surgical procedures into the following categories: (1) primary implantation; (2) exchange surgery (exchange or removal of implants); (3) secondary addition of components such as patella resurfacing or adding a second unicompartmental component (regardless of routine liner exchange); and (4) reoperation without touching implant components (such as hematoma evacuation or lavage).

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