Correspondence

Increased risk of dislocation with collar reinforced modular heads of the Lubinus SP-2 hip prosthesis

Sir—In an ongoing multicenter study registering dislocations, we have noticed a more than 10% dislocation rate in two centers using 28 mm modular Lubinus SP-2 components (Waldemar Link GmbH & Co, Hamburg, Germany), while other centers present unchanged results regardless whether a 32 or 28 mm head is used or not. This is surprising, since the Lubinus IP and its successor the SP-1 prosthesis has accounted for 25–30% of the Swedish market during the last 2 decades (Ahnfelt 1986, Ahnfelt et al. 1990, Ohlin and Önsten 1990), and nothing remarkable has been reported regarding the dislocation rate of these designs (Ahnfelt 1986, Hedlundh et al. 1991).

We have also revised a number of Lubinus SP-2 prostheses referred to us because of recurrent dislocation and deep infection. In doing so, we discovered the simultaneous existence of two different types of modular heads, both made of metal and with a diameter of 28 mm (Figure 1). Although the current agent in Sweden claims that all stock-in-trade was exchanged with the introduction of the 28 mm modular head fitting a 12/14 taper, we have seen the collar-reinforced 28 mm Lubinus SP-2 head being implanted as late as in 1994. Radiographs of this head design were also published in Acta Orthopaedica Scandinavica 1/95 in a report about early failures with Boneloc® cement (Suominen 1995). Whether or not this reflects neglect by a previous sales organization, the existence of two products with the same name but with different sized tapers in the available catalogue of Waldemar Link GmbH & Co, Hamburg (printed in 1993) obliges us to express our concern.

According to their catalogue, Waldemar Link Gmbh & Co offers 28 and 32 mm heads made of chrome cobalt alloy to fit 2 different tapers—namely, 12/14 ("small") and 14/16 ("standard"). The length of the heads "short", "medium-short" and "medium" are achieved by different depths of the bore. However, 28 mm heads fitting the standard 14/16 taper are also offered in a version where the different lengths have been obtained by varying the lengths of a collar reinforcement at the base of the head. A 28 or 32 mm head equipped with a long collar fitting only the 14/16 taper is provided for use in revision situations, where extra neck lengths may be required. The 24 mm head is available only for the 12/14 taper.

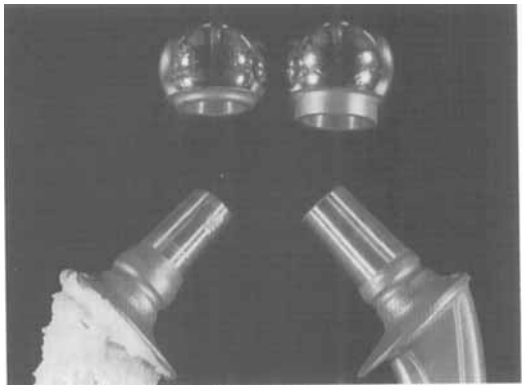

Figure 1. Photo of revised 28 mm head on the 12/14 taper (left) and 28 mm head on the 14/16 mm taper (right).

The design drawings of the 1993 catalogue do not show any collars in the small, small-medium and medium-sized heads, although their item numbers correspond to our revised collar-reinforced specimens. Moreover, the surgical procedure is illustrated by showing the implantation of a collar-reinforced head.

The two designs of the head of the SP-2 system provide entirely different ranges of motion. In a cup positioned in the recommended 15–25° of anteversion and 45° of inclination, both the 32 mm head on the 14/16 taper and the 28 mm head on the 12/14 taper are still contained at about 90° of flexion, while the collar-equipped 28 mm head levels out at about 60° (Figure 2).

We do not recommend the use of the collar-reinforced head. The extraordinarily high dislocation rate in two centers participating in our study is probably caused by the inferior design of this 28 mm head model. Other problems may arise from having two different but not interchangeable options with the same name, even if the risk of mismatching head and taper is negligible, since they do not fit. However, if adequate patient records and implant labels from previous operations are not consulted and if pre-revision radiographs are misinterpreted, there is a definite risk at revision surgery that the required components will not be available.

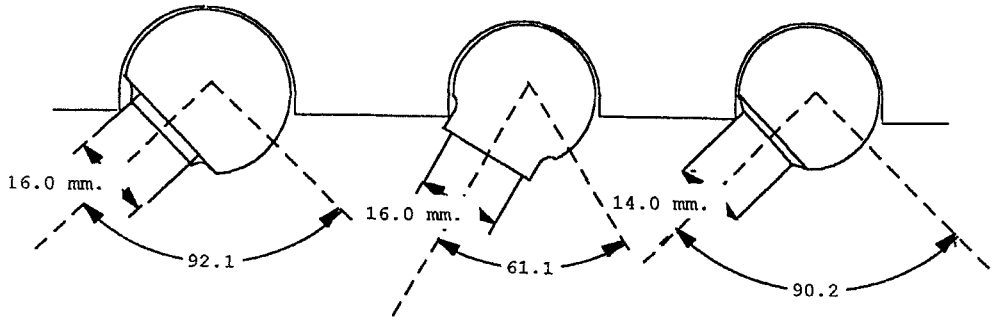

Figure 2. Estimated ranges of motion of the 32 mm head on the 14/16 taper (left), collar reinforced 28 mm head on the 14/16 taper (middle) and 28 mm on the 12/14 taper (right).

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Polyethylene particles or formaldehyde reaction

Sir—In *Acta Orthop Scand* 1995; 66 (4): 303–307 an interesting study conducted by Frøkjær et al. showed that the intraarticular injections of polyethylene particles (PEP) activated the monocytes. The PEP also increased the level of monocyte chemotactic and activating factor (MCAF) and intraleukin 8 (IL-8) in a rabbit knee synovial membrane. Many studies indicate that the biological response to the wear debris may lead to osteolysis and loosening of the implants.

However, such a rapid response as observed in this study, may be triggered by factors other than PEP alone. Frøkjær et al. used formaldehyde for the sterilization of the PEP. Formaldehyde is highly reactive and its residue may be found in materials long after exposure to the gas or vapor form of it. It is known that sensitization with formaldehyde can induce type IV allergic and asthma reactions. Dean et al. (1984) have demonstrated increased synthesis of H_2O_2 by mice macrophages after exposure to formaldehyde. A quick host reaction could be due to the residue of the formaldehyde in the debris sample. Thus, it is uncertain that the reaction observed in this study was caused by PEP. A different sterilization technique might be preferable in future studies.

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Sir—We would like to thank Dr. Anissian for his kind letter. His concern regarding factors other than polyethylene particles (PEP) as the possible cause of cytokine production in the synovial membrane is, indeed, justified. In this study, PEP were sterilized by the sterilization central at Aarhus University Hospital. They had recently examined their procedures regarding formaldehyde sterilization of polyethylene and found no formaldehyde residues left in the material.

One could then argue that formaldehyde concentrations beneath the detection level might induce and sustain a type IV allergic reaction. We believe there are arguments against such a view. First of all, sensitization by formaldehyde would have resulted in a highly inflamed synovial membrane, but we only observed slight to moderate inflammation of the synovium. Furthermore, in man the type IV allergic reaction mostly involves mononuclear cells, whereas the rabbit type IV allergic reaction is composed of neutrophils and lymphocytes and depends on the presence of IL-8 (Grønhøj et al. 1995). With Dr. Anissian's argument in mind, this would mean that there would be mostly neutrophils and lymphocytes around PEP and one should expect IL-8 to be present in cells around PEP. We found no neutrophils and lymphocytes, but cells judged to be of monocytic/macrophage character, according to the MCAF staining in these cells.

Furthermore, IL-8 was absent in the cells surrounding PEP in the deep synovial membrane, suggesting that the reaction induced by the PEP was not due to a type IV allergic reaction.

We therefore believe it unlikely that the MCAF observed in the cells around the PEP are due to formaldehyde or a type IV allergic reaction.

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Grønhøj Larsen C et al. The delayed-type hypersenstivity reaction is dependent on IL-8. J Immunol 1995; 155: 2151-7.

Stem fracture with the Exeter prosthesis

Sir–We have read with interest the paper published in *Acta Orthopaedica Scandinavica* 1995; 66 (5): 435–439 by Røkkum et al. in connection with stem fractures, using the Exeter matt-surfaced femoral components. We would like to comment on one or two matters raised in this paper.

1. When the Exeter femoral component was designed (in 1969), it was never the intention that the device would "sink into the cement mantle and self-tighten", but subsidence of the original Exeter polished stem within the cement was subsequently observed to occur in clinical practice. In designing the device, the collar was removed simply because it had been our regular expericnce in Exeter to see resorption of the femoral neck beneath the collars of the Thompson-cemented hemi-arthroplasty and the McKee-Farrar cemented total hip arthroplasty, of which large numbers were done in Exeter. This resorption of the neck led us to the view that the collar could make no consistent contribution to the transmission of load to the cut surface of the femoral neck. The taper design was adopted as being the most appropriate for the extrusion of cement into the endosteal bone of the femur during insertion of the femoral component into the femoral medullary canal full of cement. The survivors of the original series of 433 polished Exeter stems inserted at the Princess Elizabeth Orthopaedic Hospital between 1970 and 1975 now have a minimum follow-up of 20 years. Reoperation for aseptic loosening has rarely been required, but subsidence of the polished stem within the cement is extremely common. The radiographic appearances otherwise remain remarkably inocuous. The original stems were slim in section, manufactured from a ductile stainless steel (EN58J) and, to date, the stem fracture rate (with a minimum follow-up of 20 years) is 3%.

2. The matt series of Exeter stems was introduced in 1976 for two reasons. The first was the stem fractures that had been seen with the original polished series, so that a stronger stem was needed. The second was that more sizes of stem were evidently necessary. The A.P. section of the matt stem was made larger than the original polished stems. Whereas the original polished stems rarely loosened and were rarely associated with endosteal bone lysis, it became clear within 3–4 ycars of using the matt stem that endosteal bone lysis was much commoner than with the original polished stems, especially when the cement mantle was incomplete, and that this was not infrequently followed by aseptic loosening. Stem fractures, however, virtually disappeared in Exeter with the introduction of the matt stems in 1976, even though these stems were made of 316L stainless steel. In approximately 5,000 316L matt Exeter stems inserted at the Princess Elizabeth Orthopaedic Hospital between the beginning of 1976 and 1984, the stem fracture rate has been of the order of 0.22% to date. The alloy was changed to the high fatigue strength 'Orthinox' (Rex734) in 1984 and 2 years later, the polished stem was reintroduced. We do not know of any fracture of an Exeter stem manufactured from Orthinox nor, in fact, are the manufacturers of the stem aware of any such fracture.

3. Dr. Røkkum et al. suggest "The inventors of the concept reported 2% fractures of the matt stem in a series with an average follow-up of 13 years". In fact, in the paper to which the authors refer, we actually reported an incidence of stem fracture of 1.87% in the original Exetcr polished stems, not in the matt stems.

4. With regard to the long-term clinical behavior of the polished and matt Exeter stems, we believe the change in surface finish is exceedingly important. Although superficially the difference betwecn the two types of surface may appear to be slight, traces of surface roughness show that the matt surface is two orders of magnitude rougher than the polished surface. This has considerable implications not only for load transmission but also for debris production. Every matt stem that we have been able to examine that has been removed for loosening or lysis shows evidence of extensive burnishing on the stem surface, indicating the production of metal and cement debris by fretting. This is particularly important where the cement mantle is incomplete. Subsidence of the matt stem is

always associated with the production of particulate debris by this mechanism. Clinical experience and the few retrievals that we have show that this is not the case with the polished stem. The matt stem, particularly when used with a metal centralizer and contemporary cementing, cannot function as a true taper, whereas the polished stem, especially when used with the hollow centralizer, can do so. We believe this to be of fundamental importance.

5. The current Exeter Orthinox polished stems have been extensively fatigue-tested and we are confident that their fatigue resistance is entirely satisfactory.

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Sir—We appreciate the comments by Drs. Gie, Ling and Timperley. Professor Ling and his colleagues deserve credit for their most significant contribution to the design of cemented femoral stems. We fully agree about the advantages of the straight taper design without collar. However, our paper (Røkkum et al. 1995) gives rise to concern that the tapering of the Exeter stem is too extreme. With the slender distal end firmly fixed in a thick and strong cement mantle, loss of proximal support will expose the stem to considerable fatigue loading. The distal part of the stem was evidently too weak to withstand long-lasting fatigue stress, resulting in stem fracture in 3 of our 27 cases.

We regret that we erroneously related the 1.87% of stem fracture (changed to 2% during the editorial process) to the matt instead of the original polished stems, as reported by Fowler et al. (1988). Gie et al. now report that introduction of the matt stem reduced stem fracture to 0.22%, in a material of approximately 5,000 hips, operated on between 1976 and 1984. We do not know how well this series has been controlled. However, stem fracture is often, but not always, such a dramatic event that the orthopedic surgeon would probably be contacted in most cases. Our 3 cases with stem fractur, aged 58, 60, and 64 years, were among the youngest in the materialcompared to a mean of 67 years. They were active, having well-functioning and painless hips. Nevertheless, stem fracture did not occur in the 2 youngest of them until nearly 10 years postoperatively. Older patients will probably never accumulate a fatigue load sufficient to induce stem fracture. Therefore, information on the age distribution is essential for evaluating the 0.22% of stem fracture in the 5,000 hips described by Gie et al. This is also important as regards the extension of total hip replacement to younger age groups. The similarly designed but stronger Orthinox stem has been employed for only 10 years. No Orthinox stem fracture would be expected within this period, since it took 10 years to fracture 2 of our 316L stems. However, we were reassured by the favorable fatigue tests reported with the Orthinox stems.

We value the arguments of Gie et al. in favor of the polished surface. However, the question of optimum stem surface is still under discussion. Indeed, the opposite opinion to that of Gie et al. has been strongly advocated (Harris 1992). This problem can only be solved by long-term clinical results. Gie et al. report that subsidence within the cement was extremely common in the original series of 433 polished Exeter stems, with a minimum follow-up of 20 years. It is interesting that all these loose stems rarely required revision and that the radiographic appearances showed minimal changes. Again, it is difficult to evaluate the material without further data. For instance, how many patients had actually reached the 20-year control? In our small material, 1 stem subsided together with the cement mantle. 3 stems, of which 1 subsequently fractured, subsided, together with the distal part of the cement, while the proximal cement remained in place. Significant symptoms were present in 3 patients, 1 case had moderate complaints. It is remarkable if sinking of matt stems causes pain, while polished stems subside painlessly.

Few clinical results concerning the Exeter stem have been published and there is a great need for additional clinical data, especially long-term follow-ups. We hope that Gie et al. will publish their interesting data properly, so that they can be discussed adequately. We also look forward to seeing the results of independent investigators and to the outcomes of national multi-center studies.

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Fowler J L, Gie G A, Lee A J C, Ling R S M. Experience with the Exeter total hip rep!acement since 1970. Orthop Clin North Am 1988; 19 (3): 477-89.

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Røkkum M, Bye K, Hetland K R, Reigstad A. Stem fracture with the Exeter prosthesis. Acta Orthop Scand 1995; 66 (5): 435-9.

A large collar in hip replacement

Sir—I am writing to raise a question about the recent article by Carlsson et al. entitled "A large collar increases neck resorption in total hip replacement", *Acta Orthop Scand* 1995; 66 (4): 339–342. The authors report the use of a collared cemented femoral component design in a series done at 5 centers. They state that resorption was more pronounced in the cases in which a prosthesis was used with a large collar than in those with a flanged or tapered stem.

Their abstract then concludes that "in spite of theoretical advantages, a large collar is not only unnecessary but may also have negative long-term effects." In fact, they also acknowledge that "the femoral neck was cut with a conventional power saw and no special instrument was used to enhance the contact between collar and bone". Their follow-up was 5 years.

It is clear that a crude form of preparation of the femoral neck does not create intimate and reliable contact between the collar and the neck. It is disappointing that techniques using a calcar planar rasp which indexes off the trunnion of the femoral stem rasp—techniques which have been available now for 10 years—were not used in these cases.

In fact, our report (Schmalzried and Harris 1993) in which these contemporary (and necessary) techniques to prepare for collar femur contact with the femur showed after a slightly longer time (6.5 years average) that we achieved excellent collar-femur contact 91% of the time, and of those cases it was still present 6.5 years later in 88%.

The article by Carlsson et al., I believe, should be viewed as a report on the use of an implant with a large collar in which the techniques applied are no longer used.

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Sir—Dr. Harris is disappointed that the technique used for implantation of our collared prostheses did not include a "calcar planar rasp" to enhance the contact between the prosthetic collar and the resected neck of the femur. The simple explanation is that such a tool was never available for any of the designs included in the study.

We congratulate Dr. Harris on the very good results he has achieved with his own prostheses. The patients in the Schmalzried and Harris study (1993) obviously represent only a small subset of patients operated on in the unit. They were operated on by Dr. Harris and consequently with the greatest skill. Our patients were treated by a great number of surgeons, and the results represent the average standard of hip replacement in Sweden.

It is interesting that Schmalzried and Harris (1993) made the same observations as we did, but less often; out of 75 cases with collar-calcar contact they found osteopenia of the calcar in 49 cases, neck resorption in 9 cases, rounding-off under the collar in 7 cases, and in at least 10 cases they found scalloping in the collar area.

Schmalzried and Harris (1993) reported radiographic evidence that collar-calcar contact had been achieved" in 75/82 cases. The degree of contact was described in the Discussion as "good", but it is not clear how this was estimated (Figure 1 is used as an example, but neither in this case nor in Figure 4a was there any contact between collar and bone). In Dr. Harris' letter, the contact is described as "intimate and reliable" and "excellent", and the intimacy was created by the special rasp. It is likely that a special instrument will improve the initial contact, but is it really proven that this contact can be maintained? A power saw or a rasp will leave an injured bony surface and it is seems impossible to prevent this surface from resorbing. Even if the resorption amounts to much less than a millimeter, the whole contact is lost, unless the stem migrates distally, and we doubt that Dr. Harris finds this desirable.

Robinson et al. (1994) used a reamer to prepare the medial neck, and they observed neck resorption measuring 1-6 mm after 30 months in 16/50 cases operated on with a collared Spectron prosthesis. O'Hara and McMinn (1991) used the Link SP prosthesis and a special instrument to enhance the collar-calcar contact. They found resorption under the collar in half of the cases after 2 years and in all 43 cases after 4 years.

A problem, which Schmalzried and Harris (1993) neglected to mention, is that, even with a meticulous operative technique, it is very difficult to avoid trapping a small amount of cement underneath a large collar. O'Hara and McMinn (1991) noted that the cement mantle was intact in the lucent space under the collar. Reaction to cement particles under the collar might be an explanation of the scalloping in Schmalzried and Harris (1993).

Until strong evidence in favor of a collar is presented in a controlled clinical trial, present information indicates that a large prosthetic collar is not only

unnecessary but may also have negative long-term effects.

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Carlsson ÅS, Rydberg J, Önnerfält R. A large collar increases neck resorption in total hip repacement. 204 hips evaluated during 5 years. Acta Orthop Scand 1995; 66 (4): 339-42.

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Surgical treatment of tuberculous spondylitis

Sir—I write concerning the article "Surgical treatment of tuberculous spondylitis" published in *Acta Orthop Scand* 1995; 66 (2): 137–142 by Wen-Jer Chen et al.

The authors have performed two types of surgical treatment, radical debridement, radical debridement + posterior instrumentation. I do not agree completely with the indications for conservative treatment. Routine conservative treatment is not logical because there are indications for surgery in most cases when first seen (Güven 1993, Güven et al. 1994b). In most cases there is kyphosis and/or multisegmental involvement with the possibility of increasing kyphosis with or without neurological findings.

On the other hand, in selected cases single stage posterior instrumentation and fusion with or without transpedicular drainage of an abscess is an important and practical method in patients with kyphosis (Güven et al. 1994a, 1995).

The exact indications for radical debridement are not clear becaue it is well known that increasing kyphosis and pseudoarthrosis can be seen after anterior surgery only (Rajasekaran et al. 1989). I think that in selecting the type of treatment, localization of the infection, number of segments involved, neurologic status, the degree of kyphosis, and the age of the patients, all should be considered. I believe radical surgery alone has limited indications. In most patients, instrumentation is necessary. In early cases without a large abscess and collapse with only one segment involved, conservative treatment should be performed (Güven et al. 1994b). Healing of the infection alone cannot be considered as a good result. Eradication of infection without any kyphosis is the best result (Güven 1993, Moon 1990).

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Sir—Medical treatment of tuberculosis has been effective in controlling spinal tuberculosis or even curing it (Konstam and Blesovsky 1962, Friedman 1966, Tuli et al. 1967, Tuli 1975). By means of a series of 6 prospective studies performed by the Medical Research Council, chemotherapy was also established as an effective treatment for the majority of patients with spinal tuberculosis. Nevertheless, gross kyphosis, neurologic deficit and delayed bony union are possible sequelae. However, in properly selected patients, medical treatment is adequate and can be expected to yield a relatively high rate of solid bony union without surgical intervention (King and Mayo 1973). Chemotherapy remains the cornerstone of treatment for spinal tuberculosis (Boachie-Adjei and Squillante 1996). I do not agree that there are no indications for conservative treatment, as Güven claims.

The indications for operative treatment are (1) failed conservative treatment, (2) profound or progressive neurologic deficit and (3) spinal instability or marked kyphosis. The major pathology of tuberculous spondylitis is located in the anterior column in most of the cases. This is the area that usually needs to be debrided and supported by grafting. Hodgson and Stock (1960) proposed that radical debridement and anterior fusion be done as soon as possible after the diagnosis. In a long-term controlled study, the Medical Research Council showed radical debridement and fusion to be superior in the following ways:

1. Anterior bony fusion occurs earlier and a higher rate of fusion is achieved.

2. Kyphotic angulation was less common at 5 years.

3. At 10 years, kyphotic angulation increased in the simple debridement group, while it actually decreased in the radical debridement and fusion group.

Rajasekaran and Shanmugasundaram (1987) recommended radical debridement and fusion to prevent or check the development of kyphosis. The kyphosis increased after radical debridement and grafting only when the bone graft was inadequate or when the graft fractured, slipped or was absorbed. Rajasekaran et al. (1989) considered that the patients having a graft greater than two disc spaces long might benefit from additional measures, such as an extended period of no weight bearing, posterior arthrodesis and prolonged use of a brace until complete consolidation became evident. Supplemental posterior fusion and instrumentation have been suggested as an adjunct to anterior fusion in patients with destruction of two or more vertebral bodies (Bailey et al. 1972, Kemp et al. 1973, Chen et al. 1995). Posterior instrumentation and fusion alone (Güven 1994a) constitute one kind of treatment for spinal tuberculosis. The posterior instrumentation is used as an internal splint to prevent kyphosis or for correction of a flexible kyphosis. There was no direct attack on the lesion. This is not logical for the treatment of spinal tuberculosis, in which the main pathology is usually anterior. Bailey et al. (1972) and Eismont et al. (1983) advocated that in tuberculosis and other granulomatous diseases there is no question as to the superiority of the anterior approach.

We treated surgically 50 adult patients with tuberculous spondylitis and followed them for a mean of 5 (2–8) years (Chen et al. 1995). Our mainstay in the surgical treatment of the tuberculous spine is radical debridement and anterior fusion. Supplemental posterior instrumentation and fusion are performed in patients with severe vertebral loss or kyphosis. All patients obtained pain relief. Solid bony fusion was found in 46 of the patients. The average correction of the kyphotic angle was 10 degrees. An anterior approach permits direct access to the focus of the disease, decompression of the cord, rapid healing by bony union, a decreased tendency to progressive kyphosis and establishment of a definite diagnosis. If proper facilities and expertise for surgical technique are available, radical debridement and anterior fusion may have a favorable outcome in the treatment of tuberculous spondylitis. I do not agree with Güven that radial anterior debridement and fusion have limited indications.

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