Initial stability of a new uncemented short-stem prosthesis, Spiron®, in dog bone

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Abstract. Background: Use of the proximal part of the femur in total hip arthroplasty enables preservation of the distal femur for later revisions. To use this advantage, different types of short-stem prosthesis have been developed in recent years. Although cementless hip arthroplasty is not common in the treatment of canine osteoarthritis, the use of cementless short-stems might be an alternative therapy. The new cementless short-stem prosthesis called Spiron® is self-tapping, and is constructed with a conical shape with threads. We measured the relative motion in the bone/prosthesis interface with specified loads in the femora of dogs to investigate two aspects: the primary stability of two systems of uncemented prosthesis with different principles of anchoring, and the theoretical use of the Spiron® in dog bone. We measured the cyclic behaviour (i.e., reversible, elastic), subsidence (i.e., irreversible, plastic, migration) and maximal applied load.

Methods: Twenty-four pairs of fresh femur bones from adult German shepherd dogs were used. After measuring the total bone mineral density (TBMD), 16 bones were used in each of the short-stem prosthesis group (group A), the Zweymuller prosthesis group (group B), and the no-prosthesis control group (group C). Micromotion between bone and prostheses was measured for 16,200 N axial load steps, beginning with 200 N and increasing to 3000 N (1600 cycles/femur). Simple analysis of variance and non-parametric tests were used to compare the groups.

Results: The Spiron prosthesis had significantly less motion in the bone/prosthesis interface compared with the Zweymuller prosthesis.

Conclusions: The new principle of anchoring of the Spiron short-stem prosthesis may provide higher primary stability compared with conventional techniques. The findings of this study support the assumption that the use of the Spiron prosthesis to treat osteoarthritis in the dog is feasible.

Keywords: Short-stem prosthesis, proximal anchorage, primary stability, in vitro study, canine

1. Background

The advantages of cementless total hip arthroplasty (THA) are fixation via bony ingrowth and avoidance of the problems associated with polymethylmethacrylate (PMMA) [1]. However, attaining a perfect seat for the prosthesis requires precise preparation of the medullary cavity and a variety of different shapes and sizes of shaft. Further problems recognized in the past with the use of cementless systems in dogs include fissure fracture, bone resorption, and excessive motion between the implant and bone [1]. Important technical aspects of cementless THA relate to optimal fit and fill, so that the prosthesis is stable, bone ingrowth is promoted, and weight-bearing forces are transferred to the proximal femur physiologically.
Loosening of stems can result from the implantation of hip prostheses with distal application of force [2–4]. Under these circumstances, the life of a prosthesis may be shortened, and revisions may be difficult, owing to poor bone quality [4–8]. The proximal portion of the femur is well suited to the anchoring of hip prostheses owing to its stable structure [9].

A new, cementless, short-stem prosthesis was developed to address these problems [10]. The cementless, short-stem Spiron® prosthesis (ARGE Medical Technics, Hannover, Germany) is self-tapping. It has a conical shape with threads (Fig. 1). The Spiron prosthesis is made of a corundum-blasted titanium-vanadium alloy, with a Bonit hydroxylapatite coating (DOT GmbH, Rostock, Germany), which provides metaphyseal force. The coating and the thread provide an extended surface area. The design suggests high-quality primary fixation.

Measurement of the relative motion between a prosthesis and bone in vitro is the first step in testing the primary stability of a new prosthesis [2,11,12].

This study was conducted in order:

– to investigate the primary stability of the Spiron short-stem prosthesis compared with a Zweymuller-Alloclassic SL stem, by measuring the relative motion between the prosthesis and the bone, and

– to test the possibility of using a cementless short-stem prosthesis in dogs.

2. Methods

2.1. Specimens

Femur bones from adult German shepherd dogs (12 male, 12 female; 36.7 kg (SD 6.8)) were used. The dogs had been euthanized for diverse medical reasons and were examined by a veterinarian for signs of metastatic malignant disease, Legg-Calvé-Perthes disease or bone necrosis. This breed carries a genetic predisposition for hip joint dysplasia [13]. Low-grade dysplastic changes could therefore be recognized in the area of the femoral head with early formation of new bone as well as cartilage wasting in almost all animals. The bones were dissected from fresh tissue and stored in a freezer (−20°C). No formalin fixation was performed.

In total, 48 bones from the 24 dogs were used to measure relative motion. Another 16 femurs had been used in pilot experiments to test the equipment, design a recording system for measurements and
Fig. 2. Test machine arrangement. The axial loads were applied to the prostheses or femoral heads, uniaxially around the vertical mobile crossbeam of the test machine. The distal end of the femur was embedded in PMMA that was poured into a 5 cm high aluminium cylinder. The bone was tilted to 8° to enable bending in the frontal plane during axial loading.

to practise the implantation procedures. Total bone mineral density (TBMD) was measured prior to prosthesis implantation to exclude differences in bone density in each pair of femurs. The TBMD was measured at the base of the greater trochanter in the epiphyseal part of the femur, using quantitative computed tomography scans based on the principle of filtered resorption (STRATEC XCT-900 pQCT™). The XCT-900 detects cortical and cancellous bone separately and calculates the total bone mineral density based on the linear attenuation coefficient $\mu$. A threshold value determines the linear attenuation coefficient $\mu$, and cortical and cancellous bone are analysed separately. The adjustment of the threshold is combined with a colour scale. The threshold was 10/mm and the values were between 0.100 and 0.990. The thresholds were carried over as experience values by the manufacturer, STRATEC. For the cortical bone we determined a threshold value of 0.930, and for the cancellous bone of 0.790.

We cut the 48 femur bones immediately proximal to their condyles. After implantation of the prostheses, the distal end of the femur was embedded in PMMA, which was poured into a 5 cm high aluminium cylinder (Fig. 2). The bone was tilted at 8° to enable bending in the frontal plane during axial
loading. We used pairs of bones from the same dog to compare the relative motion in the two types of prostheses, in order to reduce the influence of anatomical variations.

2.2. Implants

The Spiron short-stem endoprosthesis (Fig. 1) was developed in cooperation with ARGE Medizintechnik (Hannover, Germany), based on an idea from Birkenhauer et al. [10]. The device causes a pure metaphyseal application of force. The Spiron prosthesis was implanted in the femoral neck axis. The prosthesis functions without a laterally attached fastening (latch). To avoid varus malalignment, the proximal disk portion lies flat on the stump of the femoral neck. The shaft portion is conical and threaded. With roughly the same surface area, the volume of the Spiron is 50% the size of conventional stem prostheses.

The Spiron is made of a corundum-blasted titanium-vanadium alloy and has an electronically applied precursor of inorganic hydroxyapatite (Bonit, DOT, Rostock, Germany). The prostheses we used in the tests were built to scale by the manufacturer for use in the canine femur, without the precursor of hydroxyapatite.

The Zweymuller-Alloclassic SL (Sulzer Orthopedics GmbH, Winterthur, Switzerland) was used as the control prosthesis. The Zweymuller SL is a cementless, rectangular, dual-taper straight stem prosthesis with a shaft made of Ti6-Al-4V alloy. The Zweymuller SL is a widely used prosthesis in the treatment of osteoarthritis in human. It is used for first and second operation and in the revision surgery. Because of the cortical anchoring the Zweymuller SL stem is used in all age groups and femur shapes [37].

The Zweymuller shaft prosthesis was scaled for use in the dog femur. The femoral neck–shaft angle of the endoprosthesis was adapted to the angle conditions of the canine femur (i.e., \(\sim 145–147^\circ\)). We used standard sizes, adapted for the selected bones.

2.3. Implantation

The right and left femurs of eight animals received either the short-stem Spiron prosthesis (group A) or the Zweymuller even-stem prosthesis (group B). Prostheses were not implanted in an additional 16 femurs (group C) and these were measured as the so-called “zero group”.

The prostheses were implanted according to the instructions of the manufacturer. The implantation equipment (centre drill, drill Ø 4 mm; drilling template; plate and sleeve for the template; prosthesis driller; plain milling cutter; spiron hex driver) used for the Spiron prosthesis was built to scale by the manufacturer. The plate of the drilling template was placed in the centre of the resection plane and driven into the cancellous bone using the implantation device. Using the drilling template, the central axis was drilled along the axis of the femoral neck. After the plan milling of the resection plane, the femoral neck was drilled out with the prosthesis driller. The implantation of the Spiron prosthesis is carried out clockwise. The prosthesis was screwed into the cancellous bone of the femoral neck until it reached the bedsore of the plate on the resection plane. When screwing in, a 1/4 back moving rotation was carried out after respectively 1 1/2 rotations, in order to achieve bone grafting. The prosthesis head was fixed with a light hammer blow on the cone.

For implantation of the Zweymuller prosthesis, the size of the rasps was adapted. The complete femoral neck was resected to allow the implantation of the Zweymuller prosthesis. The cancellous bone in the femoral shaft was grated with a bone rasp.

The prostheses were removed from the bone after each experiment and reused for the next experiment. Thus, two Spiron and two Zweymuller prostheses were used. After the tests the prostheses showed no wear or signs of fatigue.
2.4. Micromotion measurement

The relative motion of the prostheses in the bone model was measured with the ultrasound-supported 3D motion analysis system, CMS 30P (Zebris Medizintechnik GmbH, Tuebingen, Germany). The M1008, which can be used to measure general motion or motor disturbances, was used as an ultrasound marker. Data acquisition and processing were performed with WinData 2.19 for Windows.

Markers were fixed cranially at the greater trochanter and centrally at the equator of the prosthesis or femoral head (Fig. 2). The distance between the compact transducer and the ultrasound markers was 1 m. The measurement precision of the system was < 0.25 mm, with dissolution of 0.085 mm. The sampling rate was 20 Hz.

All data were saved in ASCII files for further statistical analysis. Only the z-axis values were used because they represented proximal and distal vertical deflection. Using the z-axis values, the relative motion of markers 1 and 2 was measured in the z-plane.

2.5. Loading procedure

After fixation of the femur in the aluminium cylinder with PMMA, it was fixed by screws to the stationary test machine table (Zwick Type 1445, Zwick, Ulm, Germany) for loading in a cranial-caudal direction (Fig. 2). The femora were tilted 8° lateral in the frontal plane to simulate the loading of a single leg stance [23] and to create bending moments.

The axial loads were transferred to the prostheses or femoral heads in a uniaxial motion around the vertical mobile crossbeam of the test machine.

The machine delivered sixteen 200 N axial load steps, beginning with 200 N and increasing to 3000 N. Ten cycles were driven for each load step (i.e., 1600 cycles/femur). From 3000 N, the load was increased linearly up to the restricted maximal power of 5000 N. Each measurement was computer-controlled with a pre-power of 10 N at a velocity of 2 mm/s. The standard force (100% Fmax) was controlled at 100 N/s and was held for a defined time.

The following parameters were measured: cyclic behaviour (i.e., reversible, elastic), subsidence (i.e., irreversible, plastic, migration) and maximal applied load. Subsidence was measured immediately after decompression of the prosthesis head at the beginning of each cycle at 0 N. The magnitude of cyclic behaviour at the prosthesis head was calculated for groups A and B from the load values.

3. Statistical analysis

We assumed a Gaussian distribution. Group comparisons were made by simple analysis of variance (ANOVA) and non-parametric tests. After the ANOVA we conducted the non-parametric Kruskal–Wallis test and the non-parametric Mann–Whitney test in order to find significant differences between the groups. P values ≤ 0.05 were considered significant.

4. Results

The mean TBMD was 420.28 mg/cm³ (SD 62.9). The TBMD did not differ significantly between male and female femurs or between groups.

There were differences between the two prostheses groups for the parameters cyclic behaviour, subsidence and maximal applied load (Tables 1–3).
Table 1
Mean cyclic behaviour in mm for different loads in the different prosthesis groups (means (SD)). N = 16/group. There were no significant differences between groups (P < 0.19).

<table>
<thead>
<tr>
<th>Load value</th>
<th>Cyclic behaviour (reversible)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200 N</td>
</tr>
<tr>
<td>Spiron</td>
<td>0.56 (0.30)</td>
</tr>
<tr>
<td>Zweymueller</td>
<td>0.59 (0.37)</td>
</tr>
</tbody>
</table>

Table 2
Subsidence in mm in the different prosthesis groups (means (SD)). N = 16/group. *represents significant differences between groups (P < 0.05).

<table>
<thead>
<tr>
<th>Load value</th>
<th>Subsidence, irreversible (migration)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200 N</td>
</tr>
<tr>
<td>Spiron</td>
<td>0.17 (0.18)</td>
</tr>
<tr>
<td>Zweymueller</td>
<td>0.49 (0.67)</td>
</tr>
</tbody>
</table>

Table 3
Maximal applied load in Newtons for the Spiron, Zweymueller and non-prosthesis groups (means (SD)). N = 32 (P < 0.05).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiron</td>
<td>1305.5</td>
<td>418.4</td>
</tr>
<tr>
<td>Zweymueller</td>
<td>853.8</td>
<td>307.7</td>
</tr>
<tr>
<td>Non-prosthesis</td>
<td>3935.0</td>
<td>1158.8</td>
</tr>
</tbody>
</table>

The magnitude of the elastic, reversible cyclic behaviour was higher for the Spiron prosthesis than the Zweymueller prosthesis, although the difference was not statistically significant (P = 0.19). Especially at 1000 N, the Spiron prosthesis showed strikingly increased cyclic behaviour (1.47 mm vs. 1.13 mm) in comparison with the Zweymueller prosthesis.

The plastic, irreversible subsidence of the Spiron prosthesis was significantly lower than that of the Zweymueller prosthesis (P = 0.05). The Spiron prosthesis showed a subsidence of 1.27 mm at 1000 N only, whereas the Zweymueller prosthesis had already produced 1.03 mm at 400 N. The subsidence was, at 3.29 mm, about three times higher for the Zweymueller prosthesis at 1000 N than for the Spiron prosthesis.

The maximal applied load for breakage of the bone was significantly higher for the Spiron prosthesis than for the Zweymueller prosthesis (P = 0.05). The range of the maximal applied load for the two types of prosthesis was relatively high. The Spiron prosthesis showed a range from 792 to 2200 N and the Zweymueller prosthesis from 399 to 1317 N. The range in the group without prostheses revealed the highest value of 1796 to 5000 N. Four femora in this group reached the maximal power of 5000 N and no bone damage was produced. The bones with the Spiron prosthesis were tilted distally. The bone around the femoral neck was destroyed minimally. We saw no bone impaction below the intertrochanteric region. The Zweymueller prosthesis was impacted in the femoral shaft vertically. After an initial fissure in the proximal part of the femoral shaft, the bone was then split in the whole mediocranial region. Massive destruction of the femoral shaft occurred.

An analysis of covariance indicated that there was no significant influence of bone density on maximal load.
5. Discussion

This study was performed in order to test the initial stability of the Spiron short-stem prosthesis compared with a conventional stem prosthesis. We wished to investigate whether the special design of the Spiron prosthesis influenced this important parameter or not, and whether this justified clinical application in dogs.

According to Smith [14], the establishment of the uncemented hip prosthesis in small animal veterinary medicine is not required because loosening of the implant and cement are not important in the dog because of its short life expectancy. However, lack of experience with the operative technique can lead to intraoperative fissures and/or fractures at the uncemented implantation of the hip prosthesis [1]. Furthermore, a sinking of the stem postoperatively is observed frequently [15]. Otherwise, the mechanical properties of the bone cement, such as brittleness, low tensile strength, low fracture strain and fracture fatigue stability, as well as low elasticity, are regarded as a disadvantage of the cemented prostheses [16]. If osteomyelitis occurs as a complication of a cemented implantation, the bone cement must be removed completely in addition to the implant, because this can represent a focus of infection [17].

DeYoung et al. [18] developed a porous-coated modular total hip system and performed uncemented arthroplasty in 92 dogs. In the radiographic assessment, subsidence and cortical atrophy of the femoral stem were seen in all femurs soon after surgery. This was the most significant bony remodelling change, but the dogs investigated were fully weight bearing.

In contrast to other studies [2,19,20], we compared the initial stability of a newly designed, cementless, short-stemmed hip prosthesis with a conventional femoral stem. Our ability to compare the results of the present study with other studies is limited owing to differences in design and measuring techniques. In a recent study, Westphal et al. [21] evaluated the primary stability of another new short-stemmed prosthesis. Like the Spiron prosthesis used in our study, the cementless stem Proxima™ prosthesis is believed to provide primary stability by physiological loading in the proximal femur. In contrast to our study, the cyclic motion (i.e., elastic deformation in our study) of the Proxima™ was lower, and migration (i.e., subsidence in our study) tended to be higher, until cortical contact was achieved, when compared with conventional stems with longer shafts. The authors concluded that bone quality and correct positioning were important factors, necessary to avoid varization and medial cut out.

The differences in elastic capacity (i.e., cyclic behaviour) of the Spiron and the Zweymuller prostheses can be attributed to application of proximal force to the femur. The lower elastic capacity of the Zweymuller prosthesis was caused by the special design and size. The Zweymuller prosthesis group showed considerably higher values than the Spiron prosthesis for subsidence (i.e., migration). This can be explained by the considerably lower elasticity of the Zweymuller prosthesis–bone combination.

In our investigation, migration of the Spiron prosthesis was lower, but its dynamic elastic movement and maximum applied load were higher than those of the Zweymuller prosthesis. We presume that these differences are related to the design of the Spiron prosthesis. The low migration is explained by a lack of distal anchoring, because distally anchored prostheses demonstrate large amounts of motion [3]. The screw-like design of the Spiron combined with a conical deadlock, proximal force transmission and small size contributes to increased dynamic elastic movement of the bone when compared with the Zweymuller prosthesis [22]. We observed decreased dynamic elastic movement of the Zweymuller, which was attributable to its stiffness, size and angled form.

To investigate the maximum applied load we choose a cyclic load transmission in order to simulate dynamic and realistic loading conditions. Overall we conducted 1600 cycles. For a quasi-static strain the load cycles were applied with a defined frequency of 1 Hz and the movement was determined with a
defined strain amplitude. In contrast to the dynamic loads, few cycles were applied. As a consequence of the process of subsidence during the first cycles, the differences between dynamic and quasi-static conditions were almost recorded [23]. With dynamic measurements, the subsidence of the prostheses under the loading conditions is recorded more accurately. The validity of a quasi-static test should be reviewed critically, therefore.

We detected the highest values for the maximum applied load in the native femora without prosthesis: 3935 N ± 1159 N. Higher values for the femora with the Spiron prosthesis (1306 ± 418 N) were measured than for the femora with the Zweymuller prosthesis (854 ± 308 N). As a result of the presence of intact proximal femoral bone, the results of the Spiron prosthesis are replicable. In contrast, the low maximal applied load of the Zweymuller group is probably related to the cementless intramedullary anchorage and is caused by the design. The resection of the bone affects the biomechanics of the proximal femur. The structure of the Zweymuller prosthesis and femoral shaft shows decreased elasticity and strain disposition. Ellenrieder et al. showed a reduction of strain lateral and medial in the femoral shaft by use of long-stem prostheses, up to 60%. Comparison of the short-stem prostheses CUT, CIGAR and Thrust Plate Prosthesis TPP with an anatomical conventional stem (GEHE, ESKA Implants) showed that the stress-shielding was significantly lower for the short-stem prostheses [24].

With our maximum applied load, the Zweymuller prosthesis broke the femur into wedge-shaped pieces, whereas the Spiron prosthesis broke the bone by distal pitching in the femoral neck area (Figs 3 and 4). This implies the application of force by the prostheses and that the load peaks in the bone under loading conditions. The different forms of fracture in the bone could be the result of the different methods of application of the load by the different prostheses. In the Spiron prosthesis, the application of force takes place in the proximal femoral bone in the direction of the femoral neck [10], whereas in the Zweymuller prosthesis the application of the load affects the femoral shaft. Quantitative investigations by numerical methods in human femurs support this assumption. The Spiron prosthesis has better loading and stress distribution [22]. The Zweymuller prosthesis showed stress-shielding along the stem shaft and in the
Fig. 4. Example of a destroyed canine femur with a Spiron prosthesis after application of maximum load. Distal pitching in the femoral neck area.

region of the greater trochanter. However, the Spiron prosthesis produced minimal resorption in the calcar region and spared the stem of the bone.

However, clinical experience with the Spiron prosthesis is rare in humans; the relevant study data were supplied by the designer [10]. In total, 38 Spiron prostheses were implanted. The pre-operative Harris Hip Score (HHS) of the patients (aged 42–73 years) was 51 (range 24–76) and increased after 12 months to 94 (86–100). In the current follow-up reports no complications attributed to the prosthesis have been registered. These data show a tendency towards faster rehabilitation with lower pain when compared with intramedullary therapies.

In the test machine, the femur was tilted by 8° in the frontal plane. We therefore produced a bending couple in the frontal plane, but not in the sagittal plane. Therefore, there was probably no rotation around the middle axis of the shaft under axial loading. Thus, physiological loading for a single leg stance was not simulated [2,25]. Owing to the conical shape and the tooth-like surface configuration at the underside of the disk, as well as the self-tapping, interrupted thread of the Spiron, it is improbable that rotation was unstable around the middle axis of the shaft [10]. Therefore, in the present study, we confined ourselves to measuring translation in the cranial-caudal direction. However, this meant that the meaningfulness and comparability of our study with other studies was restricted [2,19,20].

The system of motion analysis used in our model measured the motion of two points relative to each other. Unlike other studies, no interface motions were measured directly [2,19,20,26,27]. The design of the Spiron prosthesis makes the application of linear gauges difficult. Our results do not allow us to make predictions about micromotions of the prostheses in vivo. To simplify the test conditions, we did not simulate muscle loading. Muscle loading enhances primary fixation [28]. In experiments, the femur is fixed rigidly. In vivo, stability is provided by muscle and soft tissue. Since the loads are never constant in vivo, different micromotions are possible. Therefore the loading used simulated an extreme situation, and we presume that clinical migration of implants occurs less frequently than observed in this study. In addition, the amplitude of motion in the boundary layer between the implant and the
bone depends on resorption and the quality of the tissue formed [29,30]. Only relative motion makes osseointegration of the implant possible [31]. Stems in human bone with micromotion of 40–70 \( \mu \text{m} \) have been clinically successful for many years [32]. On the other hand, other studies have measured critical interface motion above 100 \( \mu \text{m} \) during dynamic loading [30]. Nevertheless, our measurements allowed relative comparisons because of the abovementioned numerical results and the similar qualitative test results of the Spiron prosthesis. Unlike a cylindrical screw, for which a deadlock is produced only around the thread, the conical shape of the Spiron prosthesis allows keying around the thread and the screw flanks. Stress that runs perpendicular to the axis of the screw (i.e., in pedicle screws) causes a more homogeneous strain distribution with long-term stability [33]. Therefore, the turning thread of the Spiron prosthesis cut the trajectories of the femoral neck perpendicularly. The best primary stability is produced with a right-angled contact between spongyous trabeculae and an implant [34].

Osteoarthritis can be related to local bone atrophy with reduction of the spongiosa in the collum femoris. Therefore we measured bone density at the level of the base of the greater trochanter in the epiphyseal part of the femur. Nevertheless, it was possible to misinterpret the results because the arthritic rebuilding caused by osteoarthritis was not limited in every case to the collum ossis femoris. The bone density in our study had no significant influence as a covariate on the maximal test load. During normal walking, maximal forces in dogs are 1.66\% of body weight. When running or climbing stairs, hip loading is supposedly higher [35]. Given that the forces on the human hip can increase to 2–3 times body weight, we accounted for sufficient loading by applying a maximal force of 1000 N to the dog bone (i.e., 3 times body weight [36]).

6. Conclusions

We have demonstrated that the Spiron short-stem prosthesis combines the advantage of a proximal anchored stem with lower subsidence and a cementless implantation technique in canine bones. The relative motion between bone and prosthesis determines the integration of the implant and the life of the prosthesis. Minimal relative motion in response to metaphyseal force would prolong the life of the prosthesis. In conclusion, anchoring the uncemented Spiron short-stem prosthesis in vitro can enhance its primary stability when compared with a conventional stem.

To evaluate the true utility of this new prosthesis in dogs, our results need to be confirmed by future clinical studies. This requires an in-vitro test of primary stability in comparison to the cemented conventional stem prostheses that are commonly used for hip arthroplasty in dogs. Finally, we need studies that involve in-vivo tests of the porous coated Spiron prosthesis vs. conventional cemented stems.

Competing interests

The authors declare that they have no competing interests.

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References


