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Biomechanical evaluation of osteoporotic fracture: Metal fixation versus absorbable fixation in Sawbones models

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ABSTRACT

Objective: The failure of osteoporotic fracture after internal fixation is mainly caused by the underlying bone loss and strength compromise. The aim of this study is to investigate whether absorbable internal fixation can provide adequate mechanical stability and a reduction in the incidence of failure of fixation caused by bone loss and stress shielding.
Methods: A low density cancellous bone model was selected to compare the insertion of screw (screw-in), removal of screw (screw -out) and pull - out strength of absorbable screw and metal screw. The long bone model of thin cortical bone was used to create the transverse fracture model. The model was fixed with absorbable plate-screw system and metal plate-screw system respectively. The fatigue test and static bending test were compared. Moreover, the size of screw hole area was assessed.
Results: The maximal screw - in and screw - out torque of the absorbable screw was significantly greater than that of the metal screw ($P < 0.05$), but there was no significant difference in pull-out test ($P > 0.05$). No visible failure occurred in fatigue test. There was no significant difference between the maximum load of static bending test ($P > 0.05$). The screw hole area of absorbable samples was significantly smaller than that of metal samples ($P < 0.05$).
Conclusions: In this experimental set-up it was found that the stability of absorbable screws in osteoporotic bone was better than metal screws. The absorbable system tested can achieve good stability, and the destruction of osteoporotic bone is small, which can reduce the occurrence of bone failure. Considering that absorbable material avoids the need of second surgery (implant removal) and reduces the stress shielding effect, we believe that absorbable internal fixation can be considered for fixation treatment of osteoporotic fractures.

Introduction

The number of fractures of elderly patients seen in orthopedic institutions is steadily increasing. The treatment and care of these elderly patients constitutes a challenge for the individual orthopedic surgeon, the hospital staff and the health care systems worldwide. Many of these challenges are related to the age of the patient and the frequency of comorbidities. Therefore, a successful treatment of the fracture with fast recovery of the mobility is essential for the patient's survival and wellbeing. A reasonable return to function and a successful healing in the elderly requires a rigid and stable internal fixation and rapid rehabilitation. Elderly individuals will not be able to adhere to partial weight-bearing protocols and thus require osteosynthesis which tolerates full weight-bearing. Therefore, the need for stable internal fixation in osteoporotic bone is paramount. The hardware for fracture fixation is typically designed to maintain stability during full weight bearing. However, the bone in elderly individuals often lacks mechanical strength for stable anchorage of plates, screws or nails. Age related bone changes and the additional bone weakening through diseases such as osteoporosis reduce the ability to withstand stresses, leading to subsidence, cut through or cut out of metal work and ultimately to failure of fractured bone to withstand increased loading. Often the bone around screws and nails fails prematurely leading to failure of underlying fixation. [1]

Failure of internal fixation in osteoporotic bone typically results from bone failure rather than implant breakage. [2] The deterioration of cortical and trabecular bone with aging and osteoporosis

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goes along with a considerable reduction of fixation strength of osteosynthesis materials [3]. This reduction in fixation strength has been demonstrated for most types of osteosynthesis materials including screws, plates, nails and fixators. [3–5]

It appears that at locations which are prone to osteoporotic fractures the effect of degree of bone density on fixation stability is most pronounced. In cortical bone, in which the extent of deterioration of bone mechanical properties with age is less pronounced, the thickness of the cortical bone has shown to have a dramatic effect on the fixation stability of osteosynthesis implants. [4,5] Compared to thick cortices the holding force decreases by 1000 N (or 50%) per 1 mm loss of cortical thickness. This might generate differences in holding power of bone screws of up to 2000 N within an individual bone and highlights the importance of placing bone screws in the bone with thick cortices wherever possible.

Absorbable screw is a new type of implant gradually introduced in the clinical setting, especially for the treatment of intra-articular fractures. [6] Absorbable screws make up the deficiencies of metal screws in terms of biocompatibility, degradation and mechanical properties. The above attributes draw attention to a lot of researchers to study their effectiveness in different clinical circumstances [7,8]. The screw gradually degrades over time and resorbs while its strength decreases, so that the stress is gradually transferred to the bone, which can reduce or completely eliminate the stress shielding effect [9].

However, there is not much experience with the use of absorbable screws in osteoporotic bone. Based on the mechanical properties of the resorbable material and osteoporotic bone, we hypothesized that the use of bio-absorbable screws in osteoporotic bone may provide sufficient or even better stability while reducing the risk of failure of internal fixation.

Materials and methods

Bio absorbable screw experimental set up

Model bone and preparation

We used Sawbones' model to simulate osteoporotic cancellous bone. The model bone material was a closed polyurethane foam with the lowest density of 0.08 g / cm3 (5pcf-Sawbones part # 1522-23). The bone model was cut into cubes of 40 mm in length. From the center of one side of the bone block, a 2.5 mm diameter drill was used for drilling. There were 20 pieces of model bone.

Screws

Screws were divided into two groups, the bio-absorbable screw group and the metal screw group, with each group consisting of five screws. The sample of screws tested is shown in Fig. 1.

We use the INION FreedomScrew φ3.5 * 32 mm absorbable screws and ZhengTian φ3.5 * 32 mm titanium screws, with similar design of thread (the absorbable screw thread parameters shown in

Fig. 1. Sample of screws tested.

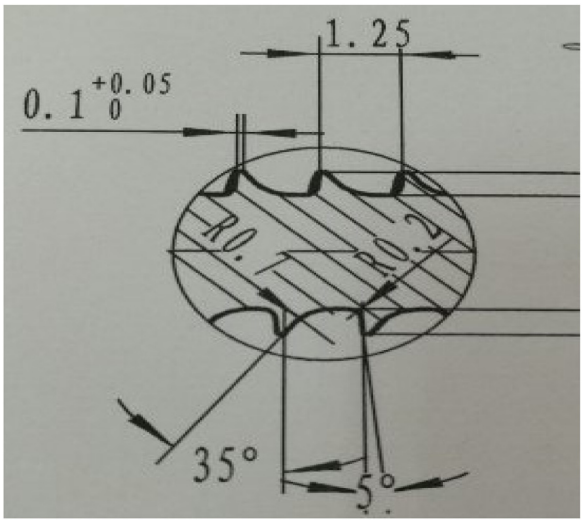

Fig. 2. The absorbable screw thread parameter diagram.

Fig. 2, the metal screw thread parameters are shown in Fig. 3.

Experimental procedure

a) This test is carried out according to ASTM F543-13. [10]
b) Screwing in and out: screw-in and screw-out test device (shown in Fig. 4). The screw is required to be loaded with pressure of 1 N before the screw-in test begins to ensure that the screw is in contact with the test piece, the test is carried out for 7 min; A pressure of 10 N was uniformly increased from 1 N in 7 min while the screw was screwed in at a speed of 3 r / min. After the screw was screwed in, the screw-out experiment was carried out. During the test, the axial pressure of 3 N was maintained. At the same time, the screw was fully screwed out at a speed of 3 r / min.
c) Pull-out: The screw pull-out test device is shown in Fig. 5, which is controlled by axial displacement loading at a loading rate of 5 mm / min.
d) The experiment was carried out using an Instron E3000 testing machine.

The experiment of plate-screw system

Model bone and preparation

We used Sawbones' model to simulate osteoporotic bone. The material of the cortical bone model was a hollow tubular fiber-reinforced epoxy with an outer diameter of 20 mm and a wall

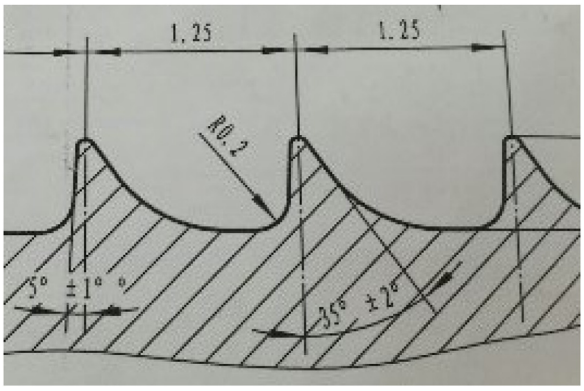

Fig. 3. The metal screw thread parameter diagram.

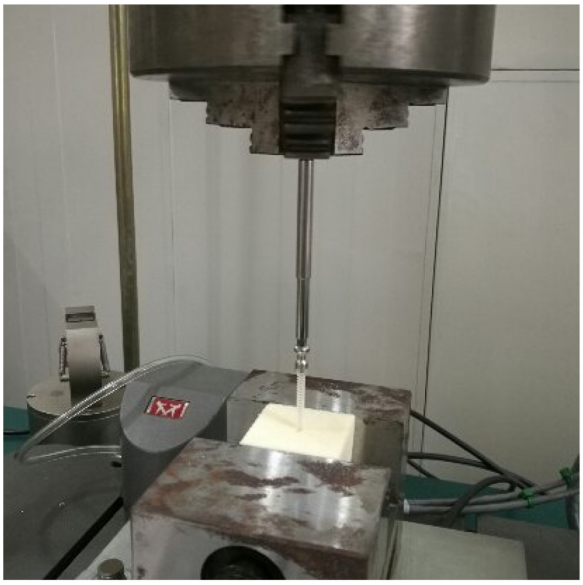

Fig. 4. The experimental device for screws in and out procedure.

thickness of 1 mm (Sawbones Cylinder # 3403-25). The cancellous bone model was made of closed polyurethane foam with the lowest density of 0.08 g / cm3 (5pcf-Sawbones part # 1522-23).

The cortical bone model was cut to a length of 125 mm. The cancellous bone model was processed into a cylinder of 18 mm in diameter and 40 mm in length with no compression in the lathe. Cylindrical cancellous bone models were filled in a hollow cortical bone model. A total of 20 model bones were prepared.

System of screw and plate

The group was divided into two groups, the absorbable material group (5 groups) and the metallic material group (4 groups).

In the absorbable material group, each sample group contained one piece of absorbable plate, selected from INION Company OTPS FreedomPlate (model: FRF-1066), 20*100 mm. Six absorbable screws were INION FreedomScrew (model HAQ02) Φ3.5 * 22 mm.

In the metal material group, each sample group contains one piece of metal plate, which is made by the 3D printing technology exactly the same as the absorbable plate. Six metal screws used were ZhengTian φ3.5 * 22 mm titanium screws.

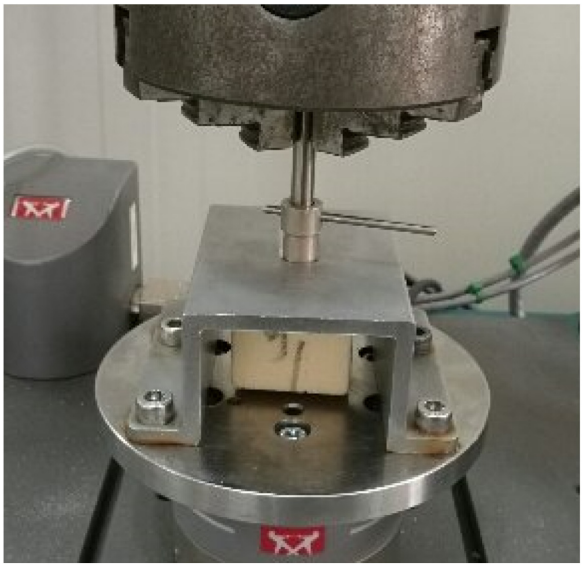

Fig. 5. The experimental device for pull out.

Fracture model and surgical procedure

i i i Two prepared bone models were placed in the processing stage to ensure consistent axis.
ii A 1 mm spacer was placed in the middle of the two-model bone to simulate the postoperative fracture line.
iii The plate was applied ensuring that the center line coincides with the fracture line.
iv The screw position was marked.
v The marked position was drilled with a 2.5 mm drill.
vi A 3.5 mm tapping was used at the entrance and exit of the screw.
vii The screw was advanced into the 3.5 mm screw hole through the plate.
viii The fixed sample is shown in Fig. 6.

Experimental procedure

Based on the standard method of ASTM-F1717, we simulated the load of flexion on the forearm when the elbow is bent (replicating rehabilitation training after surgery). The experimental model is shown in the Fig. 6.

a) Fatigue test:
After the experimental model is fixed, as shown in the Fig. 6, the axial load and torque were adjusted to zero, and then the following four steps were carried out at 7000 cycles and were executed as follows:
(1) Keep the rotation position unchanged, control the axial downward displacement, with 1 s to shift the top down 0.3 mm, then 1 s back to the initial position, the time-displacement curve was sinusoidal.
(2) Keep the axial position unchanged, and the system coaxial, with 1 s to the top left to rotate 2°, 1 s back to the initial position, time-angle curve was sinusoidal.
(3) Same as step (1).
(4) Keep the axial position unchanged, and the system coaxial, with 1 s to the top right to rotate 2°, 1 s back to the initial position, time-angle curve was sinusoidal. The time, axial displacement, axial load, rotational displacement and rotational torque of the whole process were recorded. If any form of internal fixation failure occurs during the procedure, the experiment is terminated.
b) Static bending test:
c) After the fatigue test, the static bending test was carried out. The rotational position was kept constant and the axial direction was loaded at a rate of 1 mm / min downwards until

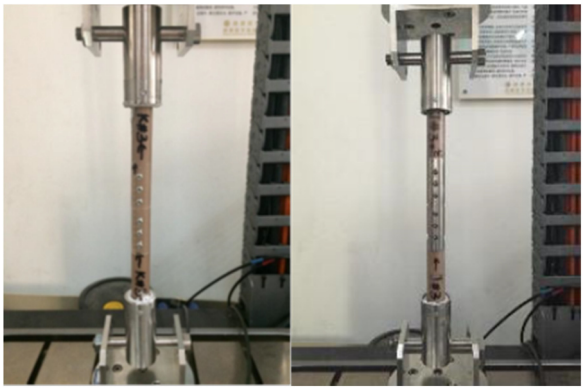

Fig. 6. The experimental device for plate-screw system.

the experimental model was visibly damaged. The displacement-load curve in the process was recorded.

d) Measure the area of the nail hole:

e) After the fatigue test, the fixation model was removed and the area of the two screw holes nearest to the fracture line was measured by 2.5-dimensional optical measuring instrument.

Results

Screw-in: Select the maximum torque of the last 10 s during the screw-in process as the maximum value of the screw-in torque, (P = 0.0139).

Screw-out: Select the maximum torque at the earliest 10 s during the screw-out process as the maximum value of the screw-out torque, (P = 0.001).

Pull out: Select the maximum axial force, as the maximum pull-out force, (P = 0.283).

The statistics of the results obtained are shown in Table 1.

Fatigue test

There were no macroscopic failures in the fatigue test, such as fracture, retraction, and plate fracture.

Static bending test

Maximum axial loads and failure modes during static bending tests (p = 0.957; >0.05) are shown in Table 2.

Measurement of the nail hole

Measurement of the screw hole, mm^2, (P = 0.006) is shown in Table 3.

Discussion

Biodegradable or bioresorbable materials have been widely used in the clinical setting, as mentioned previously. The use of biodegradable fixation system theoretically offers benefits over metal implants as the materials gradually dissolve over time to avoid the need of removal. Moreover, the mechanical load would be gradually transferred into the healing bones. Stress shielding effect of metal implants can lead to further bone loss and localized bone loss which may cause devastating outcome to osteoporotic bones. The main hypothesis in this article was to assume that absorbable fixation system can provide better stability and rigidity on osteoporotic bones, whilst preserving the bone stock as much as possible. In the internal fixation of osteoporotic fractures, the cause of failure after fixation is often on the bone, rather than on the implants. The elastic modulus of absorbable internal fixation is lower than that of metal internal fixation, which is closer to the elastic modulus of osteoporotic bone.

Table 1
Maximum torque of screw-in and screw-out, Maximum axial force of screw pull-out.

No.	screw-in(Nm)		screw-out(Nm)		pull-out(N)	
	absorbable	metal	absorbable	metal	absorbable	metal
1	0.077	0.03	0.078	0.042	96.1	104.9
2	0.051	0.043	0.074	0.043	99.6	104.3
3	0.062	0.057	0.068	0.045	100	99.1
4	0.076	0.052	0.058	0.042	97.4	94.8
5	0.074	0.049	0.067	0.039	100.5	102.3
average	0.068	0.046	0.069	0.042	98.72	101.08

Table 2
Maximum axial loads and failure modes during static bending tests P = 0.957 >0.05.

No	Maximum load(N)	average(N)	Failure mode
Metal 1	694.9	1703.62	Incomplete fracture
Metal 2	2451.04		Comminuted fracture
Metal 3	2045.97		Simple fractures
Metal 4	1622.57		Incomplete fracture
Absorbable 1	849.57	1676.144	Broken screw
Absorbable 2	2160.81		Comminuted fracture
Absorbable 3	1930.5		Comminuted fracture + Thread damage
Absorbable 4	980.4		Incomplete fracture + Thread damage
Absorbable 5	2459.44		Broken plate

Screw test

In this study, we selected the lowest-density cancellous bone in the existing Sawbones model to simulate the osteoporotic bone mass. The mechanical properties of absorbable screws and metal screws were compared by screwing in, screwing out and pulling out tests.

The results showed that, in the screw-in experiment, the last loaded torque of the absorbable screws is greater than the torque of the metal screws, and the difference was statistically significant. Previously experimental results show that the greater the screw-in torque, the stronger its stability in osteoporotic bone fixation [11]. Likewise, in the screw-out test of the absorbable screw, the initial stage of the screw-out required more torque, and the difference was statistically significant. The exit of screw often contains rotation and axial displacement, the larger the torque, the more difficult is for the absorbable screws to exit. However, in the pull-out test, the maximum pull-out force of the two screws did not differ significantly. Studies have confirmed that the pull-out strength of the screw is influenced by its design, shear strength and bone density, but has nothing to do with the material of the screw. This experiment has shown that the pull-out strength and the screw material has no obvious relationship [5,12].

In summary, in the screw experiment, the maximum screw-in torque and the maximum screw-out torque of the absorbable screw are stronger than those of the metal screw, but there is no significant difference between the maximum pull-out force, which indicated that the absorbable screws could provide better stability than the metal screws in this model.

System test

In this part of the experiment, we model osteoporotic fractures of the middle segment of the long bone. A diameter of 20 mm, 1 mm in thickness tubular cortical bone model produced by Sawbone company was selected to simulate cortical bone in patients with osteoporosis.

Table 3
Measurement of the screw hole, mm^2, P = 0.006<0.05.

No.	absorbable		metal	
1	4.68	4.25	5.47	4.82
2	4.73	4.54	5.07	5.35
3	4.95	5.13	5.23	6.12
4	4.72	5.01	4.90	4.94
5	4.49	4.77	–	–
average	4.73		5.24	

Fatigue test

In the fatigue test of nail plate system, considering that osteoporotic fracture patients usually avoid severe rehabilitation after surgery, we simulate the process of low intensity rehabilitation after 20 weeks of operative procedure, which includes one bending and one rotation every time, 5 times per minute action, 10 min every group, 2 groups daily, totally 14,000 times of rehabilitation action. We set the rotation in different directions alternately, so a total of 7000 cycles was generated.

All of 9 groups of samples, of which 4 groups of metal screw and plate and 5 groups of absorbable screw and plate, had no macroscopic failures. However, when the same axial displacement and angular displacement were applied, the axial stress and rotational torque of absorbable system can be significantly lower than that of metal system. As the elastic modulus of the absorbable material is significantly lower than the metal, so with same displacement load the force and torque of absorbable plate system is bound to be lower than the metal system. However, neither system failed in the displacement-controlled fatigue test, indicating that after 20 weeks of rehabilitation exercise absorbable plate system in osteoporotic fracture patients can maintain stability, with no significant difference compared with the metal plate system. However, the prerequisite is that the stress of the absorbable system is much less than that of the metal system. Therefore, to reduce the stress of the bone, we can use postoperative plaster or other external fixation methods to reduce the force applied to the limb.

Static bending test

In this part of the experiment, the axial pressure of the sample was changed into the bending deformation through the coupling axis. The results indicated that there was no obvious difference between the maximum pressure of the absorbable system and the metal system, and the average failure strength cannot be achieved by routine rehabilitation training, which shows the fixed intensity can withstand routine rehabilitation training activities after operation.

However, the two systems have different forms of failure. Metal samples were associated with fractures or incomplete fractures. In addition to fractures, absorbable samples also appeared having broken screws or broken plates. The screw area of the absorbable sample is significantly smaller than that of the metal sample. It can be seen that the absorbable internal fixation is less damaging to the bone during this process and part of the damage occurs on the internal fixator.

Past experience has shown that osteoporotic fracture failure often occurs in the bone. Therefore, we consider that absorbable internal fixation by reducing the bone loss and strength compromise of bone, can reduce the possibility of fixation failure to occur.

Disadvantages and limitations

In this study, the results indicated that absorbable screws had better performance than metal screws in osteoporotic bones from a biomechanical point of view. Introduced in the 1970's, the use of absorbable materials and fixation systems in musculoskeletal injuries is still not common practice for many reasons. In these experiments we performed, the real biological environment of fractures was ignored, there might be tissue reactions in actual practice of absorbable materials, according to literature, up to 40% of the patients were noted to develop sterile sinus which may lead to failure of fixation [12]. Thus, the limited mechanical properties of absorbable implants should be further studied. Moreover, many studies have proved that there appears to be no important difference in outcomes of these two materials. However, the cost-related implications regarding biodegradable fixation system is still not extensively studied. Another limitation is the experiment model used. We just performed a preliminary research about the biochemical evaluation of different fixation methods and one may argue that the number of samples used was rather small. Further studies are desirable to provide further evidence in this important aspect of fracture fixation of osteoporotic bones.

Conclusions

Through our experiments, better stability was noted in absorbable screws than metal screws in an osteoporotic simulated environment. An absorbable system with supplemented external fixation can provide good stability, and the destruction of osteoporotic bone is small, which can reduce the occurrence of bone failure. Considering that the absorbable material avoids secondary surgery for implant removal, and since it reduces the stress shielding effect, it can be considered for internal fixation for the treatment of osteoporotic fractures. However, further studies both experimental and clinical, including a cost benefit analysis should be carried out.

Conflict of interest

We declare that we have no financial and personal relationships with other people or organizations that can inappropriately influence our work, there is no professional or other personal interest of any nature or kind in any product, service or company that could be construed as influencing the position presented in this study.

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References

[1] Augat P, Simon U, Liedert A, Claes L. Mechanics and mechano-biology of fracture healing in normal and osteoporotic bone. Osteoporos Int 2005;16 (Suppl. 2):S36–43.
[2] Cornell CN, Ayalon O. Evidence for success with locking plates for fragility fractures. HSS J 2011;7:164–9.
[3] Goldhahn J, Suhm N, Goldhahn S, Blauth M, Hanson B. Influence of osteoporosis on fracture fixation – a systematic literature review. Osteoporos Int 2008;19:761–72.
[4] Seebeck J, Goldhahn J, Stadele H, Messmer P, Morlock MM, Schneider E. Effect of cortical thickness and cancellous bone density on the holding strength of internal fixator screws. J Orthop Res 2004;22:1237–42.
[5] Seebeck J, Goldhahn J, Morlock MM, Schneider E. Mechanical behavior of screws in normal and osteoporotic bone. Osteoporos Int 2005;16(Suppl 2): S107–11.
[6] Ito H, Matsuno T, Minami A. Fixation with poly-L-lactide screws in hip osteotomies. Clin Orthop Relat Res 2006;(444):169–75.
[7] Ying Z, Xiaodong Ch, Lijiang M, Dongxu P. Preparation and Characterization of Poly (l-lactide). J Biomed Eng 1999;16(Z1):98–9.
[8] Xiaohong Li, Minglong Yuan, Chengdong Xiong, Xianmo Deng. Advance of preparation and application of polylactide and its copolymers. Chin Polym Bull 1999;3(1):24.
[9] Hofmann GO. Biodegradable implants in traumatology: a review on the state-of-the-art. Arch Orthop Trauma Surg 1995;114(3):123–32.
[10] ASTM F543-17. Standard specification and test methods for metallic medical bone screws. West Conshohocken, PA: ASTM International; 2017. www.astm.org.
[11] Biano Rohan Jean. Pedicle Screw Fixation Under Nonaxial Loads: A Cadaveric Study. SPINE 2016;41(3):E124–130.
[12] Jainandunsing JS, van der Elst M, van der Werken C. Withdrawn: Bioresorbable fixation devices for musculoskeletal injuries in adults. Cochrane Database Syst Rev 2009(January (1))CD004324, doi:http://dx.doi.org/10.1002/14651858.CD004324.pub3.