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Biomechanical evaluation of the pull-out strengths of pedicular screws with expandable distal tips

Uç kısmı açılabilir (dübel tipi) pediküler vidaların sıyırma kuvvetlerinin biyomekanik olarak değerlendirilmesi

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Amaç: Tasarımını yaptığımız pediküler vida tiplerinin sıyırma kuvvetlerini dana vertebralarında değerlendirdik.

Çalışma planı: Bu deneysel biyomekanik çalışmada üç tip vidanın sıyırma kuvvetlerini dana vertebralarında değerlendirdik. A ve B grubunu oluşturan, uç kısımları açılabilir (dübel tipi) vidaların tasarımı tarafımızca oluşturuldu. 6.5 mm dış çapı olan ve iki parçadan oluşan bu vidalardan A grubunda uç kısımdan sokulan milin geriye çekilmesiyle, B grubunda arka kısımdan sokulan milin ilerletilmesiyle uç kısımlar kanat şeklinde açılmaktadır. C grubunda Cotrel-Dubousset (CD) 6 mm'lik vidaları kullanıldı. Toplam 22 vertebrada A ve B grubunda yedişer, C grubunda sekiz vida kullanarak sıyırma testi uyguladık.

Sonuçlar: Sıyırma kuvvetleri açısından, B grubunu oluşturan vidaların en yüksek değerlere sahip oldukları (ort. 1238.57 Newton), bunu A grubunu oluşturan vidaların (ort. 1124.28 Newton) izlediği görüldü. C grubunu oluşturan CD tipi vidalar en düşük sıyırma kuvvetine sahipti (ort. 978.75 Newton). B ve C gruplarıyla A ve C grupları arasındaki sıyırma kuvvetleri farkları istatistiksel olarak anlamlı bulundu ($p<0.05$).

Çıkarımlar: Uç kısımları açılabilir ("dübel" tipi) pediküler vidalar, uçları açıldığında çevre kemik dokuda sıkışma ve yeterli tutunum sağlarlar. Çalışmamızın sonuçları, B ve A grubunu oluşturan vidaların, normal kemik yapısına sahip vertebralarda, vida sıyrılmasına bağlı yetersizlik durumlarında veya kemik desteğinin yeterli olmadığı olgularda alternatif olarak uygulanabileceğini göstermektedir.

Anahtar sözcükler: Biyomekanik; kemik vidaları; ekipman tasarımı; kırık fiksasyonu, internal; lumbar vertebra/cerrahi; spinal füzyon/yöntem/enstrümantasyon.

Objectives: We studied the pull-out strengths of two types of pedicular screws, designed by the authors, in calf lumbar vertebrae.

Methods: In this experimental study we evaluated the pull-out strengths of three screw types in calf lumbar vertebrae. Expandable distal tipped screws used in groups A and B were designed by the authors. These screws were made up of two parts, with an outer diameter of 6.5 mm. The distal tips of the screws are forced to expand outwards when a pin inserted *(i)* from the distal tip is pulled from the back of the screw (group A), and *(ii)* from the back of the screw is advanced toward the tip (Group B). Group C included 6 mm Cotrel-Dubousset (CD) screws. Pull-out tests were performed in 22 vertebrae using screws in groups A (n=7), B (n=7), and C (n=8).

Results: Screws in group B were found to exhibit the highest average pull-out strength (mean 1238.57 Newton), followed by the screws in Group A (mean 1124.28 Newton), whereas the CD screws in Group C had the lowest average pull-out strength (mean 978.75 Newton). Paired comparisons between the groups B and C, and the groups A and C showed statistically significant differences with regard to pull-out strengths ($p<0.05$).

Conclusion: Expandable tips of the pedicular screws exert pressure on the surrounding bone, enabling considerable contact and increased screw-bone interface strength. Our results suggest that group A and group B screws may be an alternative application in normal vertebral bone structure, in failures associated with screw pull-out, or in cases lacking appropriate bone support.

Key words: Biomechanics; bone screws; equipment design; fracture fixation, internal; lumbar vertebrae/surgery; spinal fusion/methods/instrumentation.

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Transpedicular screw application was first described by Boucher in 1959.[1,2] Roy-Camille et al.[3] stated that they had been using the plate-pedicular screw combination routinely in the treatment of thoracic, thoracolumbar and lumbar vertebrae injuries since 1961. In recent time, transpedicular screw applications have been used widely to help alignment of vertebral column, to provide stability and create solid bone fusion in patients with trauma, tumor, spondylolisthesis, and scoliosis and patients lack of mechanical stability.[1,4-6] Although transpedicular screw application is an effective and safe method, in the follow ups of patients treated with this method some complications may occur concerning the screws used such as screw breakage, loosening, pull-out, and migration.[1,5,7-9] So many experimental studies were carried out on human cadaveric spines[1,2,4-8,10-17] and animal (calf) vertebrae [9,15,16,18] in order to investigate the reasons of these complications, evaluate stability of pedicular screws and improve the available systems.

Success of pedicular screw systems depends on the contact of the screw, which was sent in the vertebrae corpus, with the bone structure in pedicle and vertebrae corpus by means of its threads until the development of solid fusion.[14,17] However, this mechanical feature varies depending on the surgical method that is applied,[1,7-10,16-20] features of the screw[2,6,8-10,16-18,20] and factors regarding the bone structure (bone mineral density, BMD).[1,4,6,8,11-13,15,17]

In this study, two types of screws whose design was inspired by "expandable distal tipped" metal screws that are used in construction and building sectors, and a Cotrel-Dubousset (CD) type screw were compared on calf lumbar vertebrae in terms of their pull-out strengths.

Methods

Three types of pedicular screws were used in this biomechanical experimental study. Design of screws in the first and second group was done by the first author, IE. Screws are made up of a cylindrical outer part whose inside is empty, and an internal part that acts like a screw pin enabling distal tips to expand outwards.

1. In screws in group A, outer diameter of outer part is 6.5 mm, its outer surface is threaded and its empty internal surface is smooth. When the pin is pulled from the back of the screw the open distal tip expands in three or four wings. Core diameter (minor diameter) of the pin that is placed from the distal tip is 4 mm, its surface is smooth, and its conical tip's base diameter is 5.5 mm. Its back (end) part is threaded enabling locking by means of nuts at the end of pulling (Figure 1a).

2. In screws in group B, outer diameter of outer part is 6.5 mm, its outer surface is threaded, front part of its empty internal surface is smooth and back (end) part is threaded. When the screw pin that is placed from the back is forwarded towards the tip, its distal tip expands in four wings. Diameter of threaded back part of internal screw pin is 4 mm and diameter of non-threaded tip of internal screw pin is 3 mm (Figure 1b).

3. Screws in group C are 6 mm pedicular screws of CD.

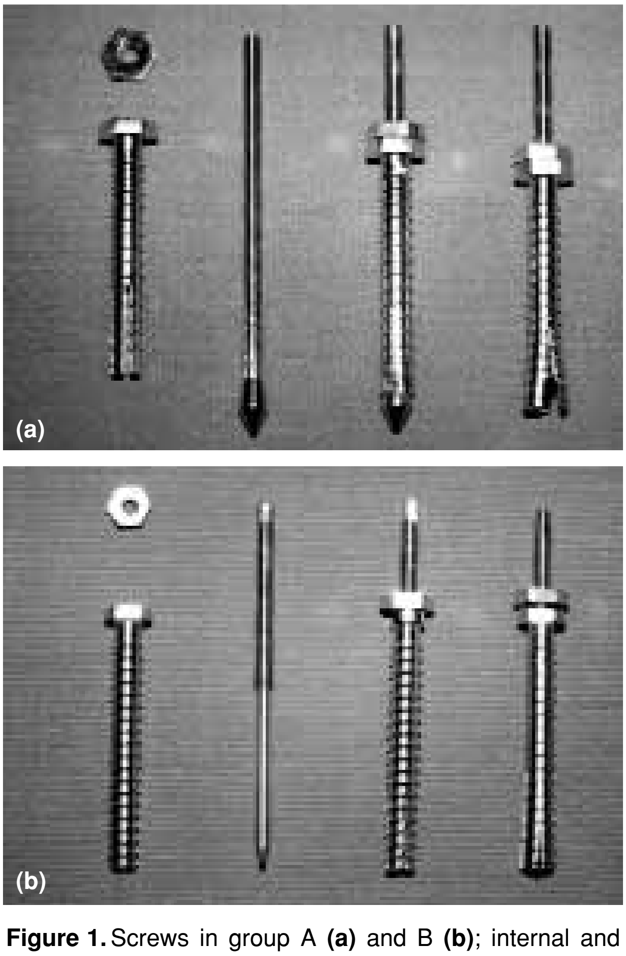

Figure 1. Screws in group A **(a)** and B **(b)**; internal and external parts, their before and after application views

Fresh calf lumbar vertebrae were used as bone material. Vertebrae that were cleaned from surrounding soft tissue and ligaments were evaluated clinically and with radiographs to determine bone fractures during their provision. Vertebrae, in whose bone structures pathology were left outside the study. After pilot holes were made by means of a 3.2 mm drill in the entry places of vertebrae which will be included in the study and tapping was used on them with a suitable tap, screws were applied transpedicularly. Before starting the test, sending directions (axes) of screws were evaluated with radiographs. Screws and vertebrae which didn't have suitable directions were not included in the pull-out strength test. Seven screws in each groups of A and B and eight screws in group C; 22 screws were used on totally 22 vertebrae. In order to do pull-out test on screw direction, lumbar vertebrae were fixed through a special clamp system. Screws were hold by their screw heads using a suitable adaptor (Figure 2). Pull-out test was conducted on screws in DARTEC brand servo-hydraulic commanded universal test machine with 0.2 mm/seconds stable speed pulling force. Results were compared. In statistical evaluations, a unilateral ANOVA test and Tukey HSD test were used. Results found out at $p<0.05$ level were considered as statistically significant. When erring (disturbance) probability was taken into consideration for three groups (0.05/3 groups), $p<0.01$ was evaluated as significantly.

Results

During pull-out tests, no breakage occurred in screws. Especially in some of the "expandable distal tipped" screws in group A, it was seen that wings that opened due to pull-out test forces got closed partially, but they didn't break. This closing rate was lower in the designs whose distal tips were of three parts.

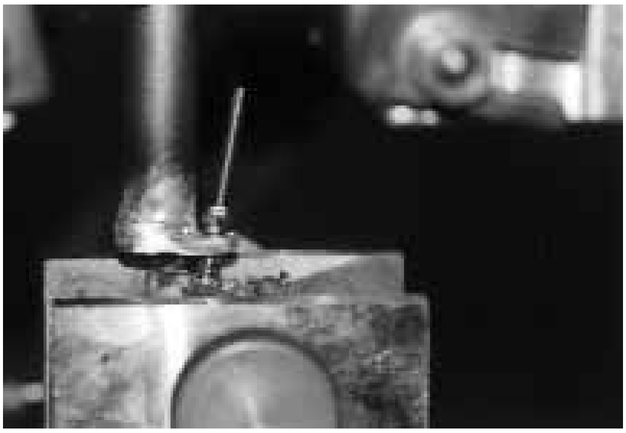

Figure 2. Clamp systems used in the fixation of vertebrae and adaptor used for holding the screws.

Results of pull-out tests applied on each group are shown in Tables 1 and 2. Graphics of pull-out tests applied on A (A-2), B (B-1) and C (C-1) are shown in Figure 3a, 3b and 3c respectively. It was understood that pull-out strength of screws in group B, whose distal tips expand when a screw pin is advanced from the inside-back part with open screw threaded toward the tip, was significantly higher than the other two groups ($p<0.05$). Pull-out strength of screws in group A, whose distal tips expanded outwards when a pin inserted from the distal tip was pulled from the back of the screw, was found out to be higher than CD type screws in group C ($p<0.05$).

Table 1. Pull-out strength values (Newton) of 22 screws in groups A, B and C

Number of screws	A	B	C
1	980	1340	875
2	1125	1095	900
3	1250	1295	980
4	1175	1240	975
5	1205	1205	1005
6	1020	1195	985
7	1115	1300	1095
8			1015

Table 2. Statistical data of mean pull-out strengths of screws in groups A, B and C

Group	Mean ± standard deviation	95% confidence interval	Distributi on width
A (n=7)	1124.2857±97.1866	1034.4031 - 1214.16	270
B (n=7)	1238.5714±82.5487	1162.2266 - 1314.9162	245
C (n=8)	978.7500±68.1778	921.7519 - 1035.7481	220
Mean (n=22)	1107.7273±135.3894		465

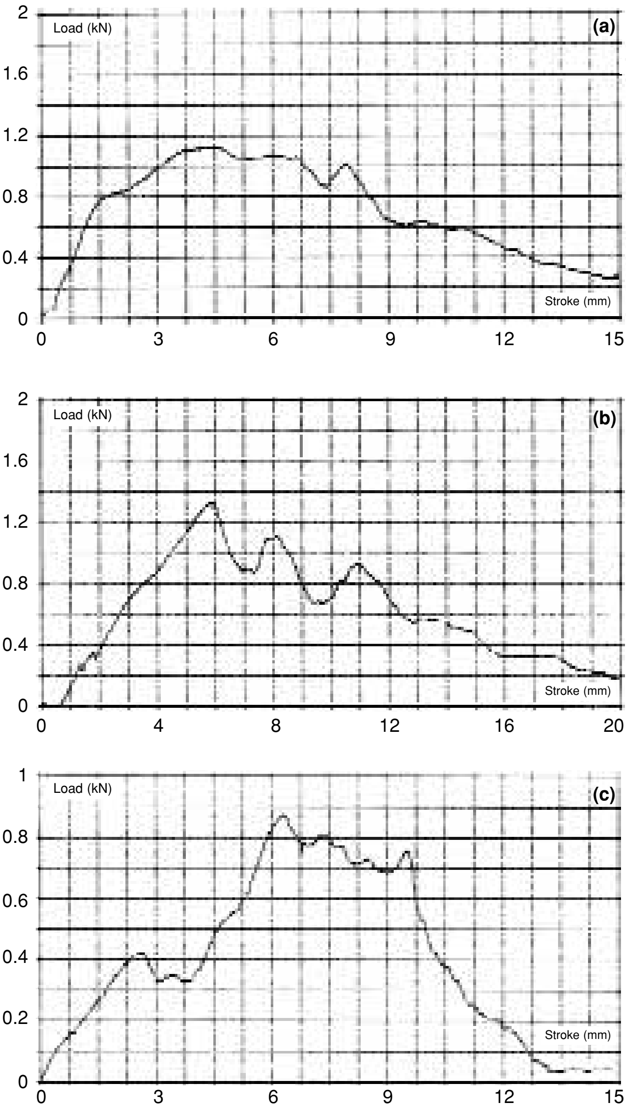

Figure 3. Graphics of the results of pull-out tests conducted on **(a)** A-2 (1125 Newton), **(b)** B-1 (1340 Newton) and (**c)** C-1 (875 Newton) screws

According to unilateral ANOVA test, the following results were found: inter group F=18.610, significantly different as 0.000. Significant values were interpreted with Tukey HSD test and significant values were found out to be 0.046 between group A and B, 0.008 between group A and C, and 0.000 between group B and C (statistically significant, $p<0.05$). When erring probability 0.01 (0.05/3 groups) was taken into consideration, differences between group B and C, and between group A and C were considered to be significant ($p<0.01$), but difference between group A and B was not considered to be significant ($p>0.01$).

Discussion

Calf lumbar vertebrae, which have similarities with human vertebrae in anatomically, physically and mechanically, have mineral density equivalent to younger human.[15,16,18] However, generally old and osteoporotic human cadaver vertebrae are used for studies.[4-6,8,11-17] Sometimes, this makes it difficult to compare results of studies conducted on human and calf vertebrae.[15] Like other researchers,[9,18] we used calf lumbar vertebrae as well in our studies due to their easily obtainable feature.

Various systems have been developed by combining pedicular screw applications, which are getting more common in spinal surgery, with plate and rods.[3,9,14,16,17] Success of these systems is related to contact of applied pedicular screw to pedicle and bone structure in vertebrae corpus until adequate fusion develops.[14,17] However, various factors affect contact of pedicular screw in bone structure. They can be listed as insertion site,[16] preparation of insertion site,[7,9,16,18] insertion torque and force,[1,8] screw insertion depth,[10,17,19,20] screw diameter,[2,6,9,10,16-18,20] screw designs (shallow or deep threads, thread diversity "fully or partial threaded", pitch and shape of its tip)[2,8,16-18] structural features of pedicle,[4,16] osteoporosis due to aging,[4,6,8,11-13,17] bone mineral density,[4,6,11,13] regional equivalent mineral density of pedicle.[1,4,15]

There are many studies searching the effects of screw diameter, screw insertion depth, conformity between screw-bone structure and surrounding bone tissue on stability. Zindrick et al.[17] reported as a result of their experimental studies on 4.5 mm cortical and 6.5 mm cancellous bone screws all of which were fully threaded that there wasn't considerable difference in the stability of the screws they had sent to 50% depth of vertebrae corpus and vertebrae anterior cortex (not exceeding cortex, to cortex); that in two screw types, they detected a considerably stronger structure in those which exceeded the cortex (through cortex) in comparison to those which didn't exceed the cortex (to cortex); that the cancellous bone screw sent until the cortex provided better contact in the cancellous bone in vertebrae corpus in comparison to the cortical screw; that when a large diameter screw that exceeded the cortex was used, pull-out strengths increased 32%. Brantley et al.[10] reported that in bones with high densities, when screw filled 70% or more of the pedicle by using long screws, or screws that would reach to 80%

or more depth by using larger diameter screws were used, stability would increase; that 7 mm screws used at L3, L4 and L5 levels (as pedicle diameters increase gradually) would fill less that 70% of the pedicle; that using large diameter screws in osteoporotic bones didn't play a role of increasing factor on fixation; that very large diameter pedicular screws would create risk of fracture in the cortical wall of the pedicle and injury in nerve root. Myers et al.,[1] Kwok et al.,[8] and Sell et al.[14] reported as a result of the biomechanical studies they conducted with different screw diameters that they didn't detect any considerable difference in pull-out strengths of screw types. Krag et al.,[19,20] showed that long screws with deeper settlement are more resistant not only to pull-out strengths along screw axis but also to torsion and flexion forces; however they would cause damage on main neurovascular structures by making holes on the anterior cortex of vertebrae corpus. Although human cadaver vertebrae were used in all of these studies, the different results that were reported may be due to age levels of the cadavers used, osteoporosis ratio in vertebrae, obtaining and storage ways of vertebrae. Outer diameters of group A and group B screws that we used on calf lumbar vertebrae were 6.5 mm, and that of CD type screw in group C was 6 mm and there were screws threaded along the screw (fully threaded screws). We applied screws in each group deeply in a way so that they would not penetrate the anterior cortex of the vertebrae. When we evaluated screws in terms of their pull-out strengths as a result of pull-out tests, it was found that screws in group B exhibited the highest average pull-out strength with their 1238.57 Newton (N) strength, followed by group A (average 1124.28 N) and group C (average 978.75 N) screws respectively. When we evaluated our results, statistically significance among the groups was advanced level (0.000) according to unilateral ANOVA test (significant differences, $p<0.05$). When statistically significance was evaluated according to Tukey-HSD test, it was determined that especially distal dull/flat tipped screws in group B had considerably (significantly) higher pull-out strength in comparison to CD screws in group C (0.000). Moreover, similar significant differences were determined between screws in group A and C (0.008). On the other hand, pull-out strength ratios between screws with expandable distal tips in group A and B was found to be 0.046. When erring (disturbance) probability (0.05/3 groups) 0.01 was taken into consideration, this difference was not accepted to be considerable (no significant differences) as $p>0.01$. Expandable distal tipped screw application, which is used commonly and effectively in construction and building sectors in horizontal or vertical surfaces, surfaces of different slopes and even in surfaces whose back is not full enough, is based on the fact that they contact the surrounding structure when their tip is expanded through various processes. We are of the opinion that when the distal tips of the expandable distal tipped screws, which we designed and created by inspiring from metal

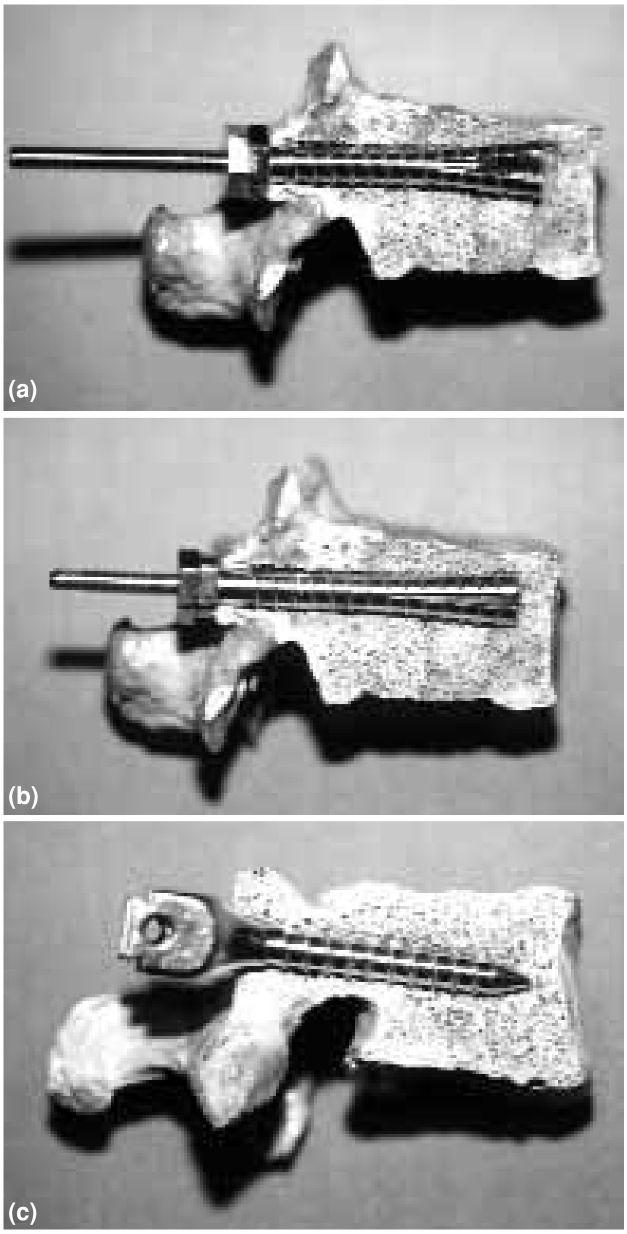

Figure 4. Representative applications of sample screws in group **(a)** A, (b) B and **(c)** C in dried human vertebrae

screws, expand after the application, their resistance to especially pull-out strengths towards the screw will increase by providing compression in the surrounding tissue. The fact that the screws in group A and B exhibit higher pull-out strengths in comparison to CD screw in group C verifies our opinion. Representative applications of sample screws in group A, B and C respectively in dried human vertebrae are shown in figures 4a, 4b and 4c.

Skinner et al.[2] compared 6.5 mm Steffee screw, 6 mm Howmedica external fixator screw, 5 mm AO Shantz screw and 3.5 mm Roy-Camille pedicular screw and reported that Steffee screw had the highest pull-out strength values, followed by Howmedica and Roy-Camille screws; that pull-out strengths of 6.5 Steffee screws whose pitch is 2.82 mm are considerably higher in comparison to 3.5 mm Roy-Camille screws whose pitch is 1.26 mm; that AO and Howmedica screws had the largest minor (core) diameters (3.75 mm and 4.29 mm), their ratio of minor (core) to major (outer) diameter was 75% and therefore possibility of breakage of increased minor diameter was low when bending forces are exerted. Not only axial forces but also torsion and bending forces are effective on bone-screw interface (contact zone).[5,17] When the thread depth increase, minor diameter will decrease; therefore there may be breakages in the screw upon the effects of torsion and bending forces. We believe it is necessary and plan to conduct additional biomechanical studies in order to determine the resistance of the movable 4 mm diameter internal pin to torsion and bending forces although pull-out strength tests on screws in group A and B are considered to be sufficient in our study.

Another factor effecting the pull-out strength is the hole preparation of insertion site. George et al.[7] reported as a result of the study they conducted by using drill and guide wire in the preparation of the pilot hole that there isn't considerable difference between the pull-out strengths of the two methods; however breakage of the cortex of pedicle may weaken pedicular screw fixation during preparation. Sar et al.[18] states that preparation of the tunnel, through which the screw may pass, by means of a drill and opening thread here by means of a tap will provide a considerable increase in the pull-out strength of the screw. In our study, first by opening insertion holes with drill in three groups, we prepared the tunnel with the help of a suitable tap. It is technically not possible to advance without opening a way (tunnel) by means of a tap for the screws in groups A and B, and especially dull/flat tipped screws in group B. We believe that when a way (tunnel) is opened by means of a suitable tap, the desired bone-screw contact will be provided as especially the cancellous bone structure in the pedicle will enable compression in the surrounding cortico-cancellous bone structure. We are of the opinion that when expandable distal tipped screw is used, this compression will increase and show more resistance to pull-out strength and other strengths.

When a failure depending on the screw compression develops, Zindrick et al.[17] stated that bone cement applied under pressure (pressurized methyl methacrylate "methacrylate") doubled pull-out strengths; however Sar et al.[18] reported that in case a screw is pulled-out reinsertion of a larger diameter screw is more effective than insertion of the same diameter screw with cement. It was also emphasized that bone cement might cause nerve injury by getting out of the bone section it was applied.[6,10,13,18] Therefore, carbonated apatite cancellous bone cement which was determined to increase pull-out strength 70%, doesn't eject heat around (nonexothermic), and which is injectable and has biomechanical conformity was suggested by some authors.[13] We are of the opinion that expandable distal tipped screws whose diameter is expanded may be an alternative way of solution in cases of failure in screw place (we haven't completed their biomechanical studies yet) in order to avoid the negative effects of bone cement (PMMA).

Another factor affecting screw stability was said to be the own structural features of the bone, osteoporosis due to aging and especially mineral density of the bone and its regional equivalent mineral density. Level of osteoporosis plays a significant role in screw stability.[6,11,12,17] It was reported that pull-out strengths decreased as the level of osteoporosis increased.[6,8] In order to increase pull-out strength and fixation strength in these cases, augmentation by means of bone cement (polymethylmethacrylate, PMMA) according to the grade of osteoporosis,[4,6,16,17] using cement with biocompatible (propylene glycol-fumarate, carbonated apatite),[13,16] applying pedicle screw systems combined with a hook[4,11,12] or triangular system[4] were suggested. We believe that stable methods should be used in the first attempt in order to avoid other operation attempts that may be required after the probable complications that may develop due to systems and methods used in aged and osteoporotic patient group. Although the bone structure of calf lumbar vertebrae used in our study are not same with osteoporotic vertebrae, as the pull-out strengths are higher in screws in group A and especially in group B, we think that these screws can be used accompanied by hook in cases with osteoporosis at not too serious levels.

Conclusion

Factors affecting the pedicular screw stability vary according to the insertion technique, features of the screw and surrounding bone structure (bone mineral density, BMD). Importance of pull-out strengths in the evaluation of pedicular screw stability is known. However, also torsion and bending forces that affect bone-screw interface (contact zone) in medio-lateral or caudo-cephalad direction should be evaluated. In this study, we compared the pull-out strengths of expandable distal tipped pedicular screws with CD screw. We found the pull-out strengths of screws in B and A, especially that of dull/flat tipped screws in especially group B, as statistically significant. However, we didn't evaluate the resistance of our screws to bending and torsion forces. We believe it is necessary and plan to conduct additional biomechanical studies in order to determine the resistance of the movable 4 mm diameter internal part (screw pin) to torsion and bending forces. According to the results of our study, we believe that expandable distal tipped outer parts will create more resistance to axial forces by providing compression and sufficient contact in the surrounding bone tissue. We are of the opinion that increasing outer (major) and internal (minor) diameters of our screws proportionally in the low lumbar vertebrae where pedicle diameter increases gradually will increase the mechanical resistance of the screws.

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