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Soft tissue tendon graft fixation in the tibial tunnel with a bioabsorbable screw-EndoPearl combination in tibiae of low bone mineral density: a biomechanical study

Kemik mineral yoğunluğu düşük tibialarda yumuşak doku tendon greftinin emilebilir vida-EndoPearl kombinasyonuyla tibia tüneline tespiti: Biyomekanik çalışma

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Amaç: Bu biyomekanik çalışmada, yumuşak doku tendon greftinin tibia tüneline tespitinde emilebilir vida ile emilebilir vida-EndoPearl materyal kombinasyonu incelendi.

Çalışma planı: On adet inek tibiası yumuşak dokularından temizlendikten sonra 7 mm çapında açılan kemik tünelleri 9 mm'ye kadar genişletildi. Tibialis anterior allogrefti, kemik mineral yoğunluğu yüksek beş tibiaya (1.36±0.4 gr/cm^2) bir adet vida (10 mm çapında, 30 mm uzunluğunda) ile, kemik mineral yoğunluğu düşük beş tibiaya (0.84±0.13 gr/cm^2) vida-EndoPearl kombinasyonu ile tespit edildi. Örnekler, servohidrolik makinada 20 mm/dak hızla son yetmezlik yüklenmesinden önce, 10 kez 10-50 N arası, daha sonra 500 kez 50-200 N arası kuvvetle yüklenmeye maruz bırakıldı.

Sonuçlar: Tekrarlayıcı yüklenme testi süresince yer değiştirme ve sertlik açısından; son yüklenme testi süresince, son yüklenme kuvveti, yer değiştirme ve sertlik açısından iki fiksasyon grubu arasında anlamlı farklılık bulunmadı (p>0.05).

Çıkarımlar: İki fiksasyon grubunda tekrarlayıcı yüklenme ve son yüklenme testi süresince yerdeğiştirme ve sertlik yönünden sonuçların benzer bulunması, kemik mineral yoğunluğu düşük tibialarda vida-EndoPearl kombinasyonuyla yapılan yumuşak doku tespitlerinin greft kaymasını engelleyebileceğini göstermektedir.

Anahtar sözcükler: Emilebilir implant; ön çapraz bağ; biyomekanik; inek; kemik vidaları; materyal testi; tendon/transplantasyon; tibia/cerrahi.

Objectives: This biomechanical study evaluated soft tissue tendon graft fixation in the tibial tunnel using a bioabsorbable interference screw with or without supplemental EndoPearl device.

Methods: Ten bovine tibiae were stripped of all soft tissues and bone tunnels 7 mm in diameter were drilled with dilation to 9 mm. Tibialis anterior allografts were fixed with a screw (10 mm in diameter, 30 mm in length) in five tibiae of high bone mineral density (1.36 g/cm^2), and with a screw-EndoPearl combination in five tibiae of low bone mineral density (0.84 g/cm^2). The specimens were cycled 10 times from 10 to 50 N, and 500 times from 50 to 200 N in a servo hydraulic test device prior to ultimate load-at-failure testing at a rate of 20 mm/min.

Results: No statistically significant differences were found between the two fixation groups with respect to displacement and stiffness during cyclic testing, and with respect to load at failure, displacement, and stiffness during load-to-failure testing (p>0.05).

Conclusion: The finding of similar results in both fixation groups with respect to displacement and stiffness during cyclic testing and during load-to-failure testing suggests that a screw-EndoPearl combination in tibiae of low bone mineral density may be helpful in the prevention of graft slippage.

Key words: Absorbable implants; anterior cruciate ligament; biomechanics; cow; bone screws; materials testing; tendons/transplantation; tibia/surgery.

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The use of soft tissue tendon grafts has become increasingly popular for ACL reconstruction because of its considerable strength, similar biomechanical function to the native ACL and better maintenance of biomechanical properties with increasing patient age than bone-patella tendon-bone (BPTB) grafts [1,2]. On clinical follow-up at 28 months post-surgery, Doral et al [3] and Aglietti et al [4] reported no difference between the functional outcomes of patients who underwent ACL reconstruction with either soft tissue tendon or BPTB grafts.

Graft selection depends on issues of strength, stiffness, fixation method, donor site morbidity, and osteo-integration. Tibial side fixation is considered to be the weak link during ACL reconstruction when soft tissue grafts are fixed with an interference screw. Of particular concern following tibial side soft tissue graft fixation with a bioabsorbable interference screw is the initial strength of graft-tunnel fixation prior to osteointegration at approximately 12-16 weeks post-surgery[5]. Because of delayed tunnel osteointegration for soft tissue tendon grafts compared to BPTB grafts, concerns exist that the repetitive cyclic loading of early progressive rehabilitation will lead to graft slippage, creating excessive knee joint laxity [2,6,7]. The mechanical properties of soft tissue graft fixation in the tibial tunnel has been improved through the use of soft tissue washers, staples, sutures over a post, and a button [4,8,11]. Although extra-articular graft fixation with a soft tissue washer reportedly provides greater fixation strength [12] this construct tends to allow increased graft slippage [7]. These devices may contribute to inferior construct biomechanical properties due to increased length between fixation points and the influence of suture material [11]. A concern over tibial side soft tissue graft fixation has lead to the use of a larger screw diameter or length [13,14], an interference screw augmented with extraarticular fixation or solely extraarticular fixation [4,9,10].

Biomechanical testing of soft tissue graft-tibial tunnel fixation under cyclic loading conditions can simulate construct performance during the early post-operative rehabilitation period prior to soft tissue tendon graft-bone tunnel osteointegration. In this manner, cyclic testing provides a more valid forum for evaluating the effectiveness of tibial side fixation under the day-to-day loads encountered by the patient during routine activities of daily living, walking, and functional rehabilitation tasks.

The spherical biodegradable poly-L-lactide device (EndoPearl, Linvatec Largo, FL) was developed to prevent femoral side soft tissue tendon graft slippage via an internal interlocking action with an interference screw. Using a bovine tibial model, Weiler et al [15] reported soft tissue graft fixation using a bioabsorbable interference screw that was augmented with an EndoPearl resulted in an ultimate load at failure of 658 + 118.1 N compared to 388.5 + 125.6 N using a screw alone. Kocabey et al [16] reported the use of supplemental EndoPearl fixation of short length soft tissue grafts within a tibial tunnel.

The purpose of this biomechanical study was to evaluate the cyclic loading properties of combined bioabsorbable interference screw-EndoPearl use to prevent soft tissue graft slippage when a short length graft is used in comparatively lower density tibial bone compared to bioabsorbable interference screw use alone in higher density tibial bone. When tibial bone mineral density (BMD) is high many fixation devices used alone may provide adequate performance during load at failure testing. When tibial BMD is low, combined or "hybrid" fixation methods may enable similar load at failure results. Our hypothesis was that combined screw-EndoPearl fixation in low BMD tibiae would display comparable cyclic testing fixation results to screw fixation alone in higher BMD tibiae.

Materials and methods

Ten fresh frozen bovine tibiae were used in this study. All specimens were harvested from healthy

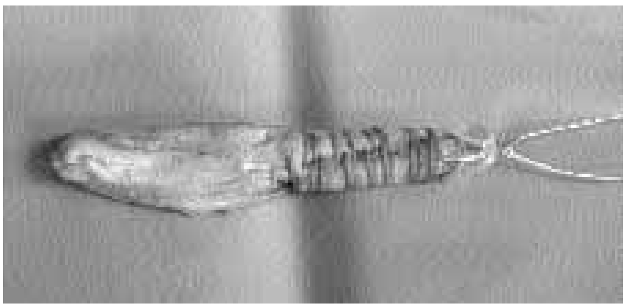

Figure I. Short, double bundle tibialis anterior allogreft with endopearl adult animals that were being processed for food. Within 1 hour post-harvest, specimens were placed in a sealed plastic bag for immediate freezing. Prior to study use, all tibiae were thawed at room temperature (23.9° C) for 24 hours. All tibiae were tested within two weeks of harvesting. After the removal of all soft tissue, BMD was evaluated using an x-ray fan beam (DEXA) scanning system (Hologic QDR-1000 Whole body X-ray Bone Densitometer, Hologic Inc., Waltham, MA). Tibiae were placed in a saline bath during DEXA scanning. A 15 cm x 25 cm DEXA scanning field was used to evaluate the metaphyseal and diaphyseal regions of the proximal tibiae.

Ten doubled, tibialis anterior allografts (length: 70-mm, diameter: 9-mm) (Cryolife, Marietta, GA) were stripped of any remaining soft tissue and were prepared for ACL reconstruction with a running, interlocking whipstitch using #2 FiberWire (Arthrex Corp., Naples, FL) as previously described [17](Fig. 1). A graft table was used to double and pre-tension the grafts during and after preparation. Following this, grafts were divided equally into two groups of 5.

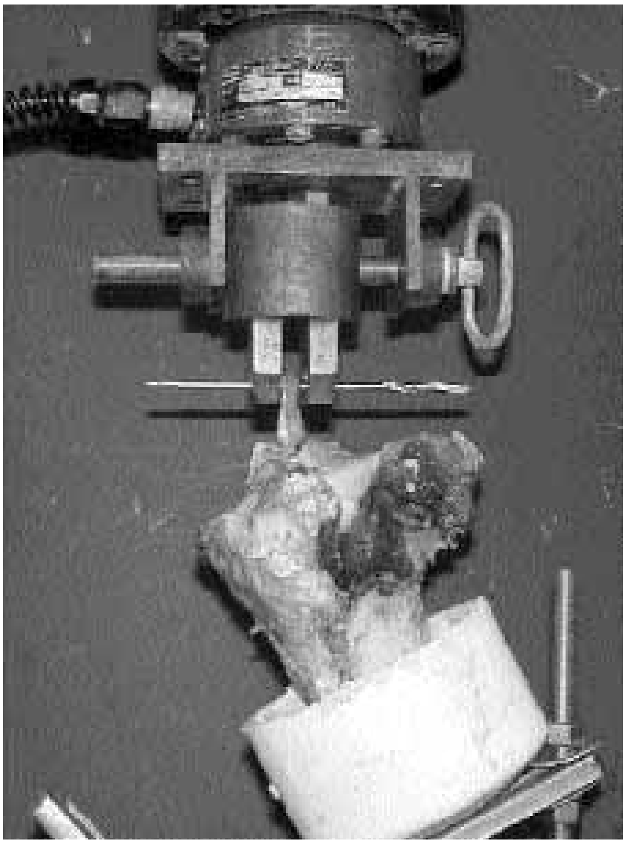

Figure II. Servohydrolic test machine

The BMD of tibiae that received bioabsorbable interference screw fixation alone was 1.36 + 0.4 g/cm2 (range 0.98-1.98 g/cm2). The BMD of the tibiae that received combined bioabsorbable interference screw-EndoPearl fixation was 0.84 + 0.13 g/cm2 (range 0.7-1.0 g/cm2). Tibial tunnels were drilled in the anatomical locations used for ACL reconstruction as described by Howell et al [18]. Tunnels were then dilated with reamers and tunnel dilators from 7-mm to 9-mm in 0.5 increments (Linvatec, Largo, FL).

Following tunnel preparation the tibialis anterior allograft was passed into the tibial tunnel and fixed with either a 30 mm long, 10 mm diameter tapered bioabsorbable poly-L-lactide interference screw (Linvatec, Largo, FL) alone (group 1) or with the same bioabsorbable interference screw type combined with an EndoPearl device (group 2) using standard techniques. Interference screw insertion torque was measured using a digital torque gauge (Series MG, Mark-10 Corp., Hicksville, NY).

Following fixation, each tibia specimen was mounted to an anchoring base with the proximal portion of the graft extending above the tibial articular surface secured to the load actuator of a servo-hydraulic testing device (Model #858, MTS, Minneapolis, MN) positioning the tensile force vector directly in-line with tibial tunnel position ("worst case scenario"). A steel pin secured to the servo hydraulic testing machine was threaded through the looped end of the proximal aspect of the tibialis anterior allograft (Fig. 1). The soft tissue graft-tibial constructs were then cycled 10 times from 10-50 N, and 500 times from 50-200 N prior to ultimate load at failure testing at a rate of 20 mm/min. Statistical analysis was performed using SPSS ver. 11.0 software (SPSS, Chicago, IL). An alpha level of <0.05 was selected to indicate statistical significance.

Results

Group 1 displayed slightly greater mean screw insertion torque (31.9 + 3.3 Ncm) than group 2 (29.1 + 2.4 Ncm) however this difference was not statistically significant (p = 0.09). All specimens survived cycling testing. During cyclic testing, statistically significant differences were not observed between groups for displacement (group 1 = 3.0 ± 2.2 mm vs. group 2 = 2.4 ± 0.8 mm, p = 0.93), or for stiffness (group 1 = 97.5 ± 55 n/mm vs. group 2 = 86.8 ± 20.5 N/mm, p = 0.93).

During ultimate load at failure testing all constructs failed by graft pullout from the tibial tunnel. Although constructs fixed with a bioabsorbable interference screw alone in higher BMD tibiae (group 1) displayed greater load at failure (816.7 ± 311 N vs. 586.1 + 160 N) than constructs fixed with a combined bioabsorbable interference screw-EndoPearl device (group 2), the difference was not statistically significant (p 0.09). Additionally during load at failure testing, statistically significant differences were not observed between groups for displacement (group 1 = 14.8 ± 4.8 mm vs. group 2 = 12.5 ± 55 mm, p = 0.31) or stiffness (group 1 = 53.1 ± 25 N/mm vs. group 2 = 47.8 ± 23 N/mm, p = 0.84). The combined bioabsorbable interference screw-EndoPearl device group displayed one specimen that failed via EndoPearl breakage (at approximately 700 N), one specimen that failed by knot slippage (324.8 N), and three specimens displayed ruptured sutures between the EndoPearl device and the graft.

Discussion

Early progressive rehabilitation may greatly diminish post-operative morbidity [19]. Initial fixation strength permits safe early participation in a progressive rehabilitation program and an accelerated postoperative recovery [7,11,20]. Morgan et al [21] reported that proximal tibial graft fixation with a bioabsorbable interference screw provided a more anatomically valid fixation that helped reduce graft elongation. Repetitious, submaximal loading forces are regularly applied to both the graft and graft-

tunnel fixation during postoperative rehabilitation [22]. For this reason, ACL graft fixation studies should focus more on cyclic loading tests.

The method used to fix an ACL graft must be sufficiently strong and stiff enough to restore knee stability and to withstand the slippage tendency that occurs during the initial 3 months after surgery [5]. Based on the reports of Morrison et al [23], Noyes et al [24] estimated that the ACL experienced a peak tensile load of approximately 450-N during activities of daily living and jogging. More recent studies have supported this estimate [16,22,25,26]. Frank et al [25] reported that the peak tensile load of the nonimpaired ACL of young adults was approximately 2500 N. Beynnon et al [8] and Magen et al [22] estimated that ACL tensile loads during routine activities of daily living approximated 20% of the capacity of the nonimpaired ACL (approximately 500 N). Ventura et al [26] reported that friction at the tibial tunnel-soft tissue graft interface eliminates approximately 10% of the graft tensile load (approximately 50 N).

Full knee extension by quadriceps muscle activation has been shown to produce resultant ACL or graft tensile forces up to 200 N [16,27]. Seil et al [28] suggested that initial graft fixation strength should be higher than 200 N to withstand the repetitious loads associated with a progressive rehabilitation program. Using a bovine model, Giurea et al [6] reported that even cyclic tensile forces as low as 150 N resulted in progressive slippage of soft tissue tendon grafts that were fixed with interference screws in tibial tunnels.

Ultimately, construct stiffness characteristics under moderate cyclic loads may be more important to determining when a patient can safely participate in early progressive rehabilitation than ultimate load at failure [29]. Use of the cortical bone located at the tibial tunnel apertures during interference screw fixation can help prevent graft slippage [15,30,31]. When a soft tissue tendon graft with less than ideal length is used for ACL reconstruction, screw placement must rely primarily on the cancellous bone located closer to the tunnel center. When this occurs supplemental fixation is recommended to decrease the potential for graft slippage. When confronted with this situation the EndoPearl device provides intra-tunnel means of bioabsorbable, supplemental fixation. Using calf tibia of equivalent BMD with each group (0.8 g/cm2), Weiler et al [15] reported that the bioabsorbable screw-EndoPearl combination group

displayed ultimate load at failure of 658.9 ± 118.1 N, while the screw fixation along group displayed an ultimate load at failure of 385 ± 185.6 N. Our results suggest that tibial BMD has a greater influence on initial ultimate load at failure than the use of a supplemental fixation device. Supplemental fixation may help improve ultimate load to failure results, however its ability to prevent construct displacement in poor BMD tibiae, effectively mimicking the results obtained with single device fixation in high BMD tibiae may be the more clinically relevant factor.

This study is limited. We used bovine bone because of adequate availability and more consistent bone quality, skeletally mature bovine tibiae were used rather than cadaveric human tibiae. Shapiro et al [32] reported that bovine stifle bone was a good simulation for healthy young human bone during biomechanical testing. Several authors have reported results that are not significantly different from those found with young human bone [6,7,15]. Secondly, we tested only tibial side soft tissue graft fixation using 70-mm long grafts, rather than routinely used 110-mm long grafts. This configuration left a 40-mm free graft length, which adequately simulated normal ACL graft length between two fixations side. To minimize the influence of additional variables, Weiler et al [7,15] left 25 mm of available soft tissue graft length between the tibial surface and the clamp they used for biomechanical testing. Femoral fixation was not performed in our study so that study results would focus solely on tibial side fixation. Our cyclic testing protocol only used 500 cycles between 50-200 N. Several reports [33,34] have recommended 1000 load cycles between 50-250 N to simulate 1 week of early, progressive rehabilitation. Since it takes up to 12 weeks for soft tissue tendon graft-tibial tunnel osteointegration to occur, approximately 12,000 cycles would conceivably best address the ability of the construct to withstand moderate, cyclic loads. Our use of 500 cycles between 50-200 N was selected to simulate the early, progressive rehabilitation loads with consideration of the active quadriceps forces reported by several studies [27,28,35] According to Weiler [15] and our study, EndoPearl may effect cyclic loading and load to failure results when using tibiae of low BMD and may effect cyclic loading results when using tibiae of high BMD.

The results of our study suggest that the use of supplemental intra-tunnel fixation such as the EndoPearl device in combination with a bioabsorbable interference screw can achieve soft tissue tendon graft-bone tunnel fixation in tibiae of low BMD which can withstand moderate, cyclical loads similarly to the use of a bioabsorbable interference screw alone in tibiae of higher BMD. By enabling use of higher density cortical and cancellous tibial bone, combined bioabsorbable interference screw-EndoPearl device use may be particularly advantageous when a less than ideal length soft tissue graft is fixed in a tunnel prepared in poor BMD tibiae.

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