

Single-Stage Revision Anterior Cruciate Ligament Reconstruction Using Fast-Setting Bone Graft Substitutes



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Abstract: Revision anterior cruciate ligament reconstructions can be performed using either a single-stage or 2-stage technique. There are several benefits to using a single-stage approach when technically possible. Although not always feasible, eliminating the necessity of a 2-stage approach for certain indications is clearly preferable because it requires fewer operative procedures, leads to a more rapid recovery, and is cost effective. Here, we describe the use of fast-setting bone graft substitutes in the setting of single-stage revision anterior cruciate ligament reconstruction. The authors have found this technique useful in converting what would sometimes otherwise be approached using 2 stages into a single-stage procedure.

Approximately 140,000 patients undergo anterior cruciate ligament reconstruction (ACLR) in the United States each year.¹⁻⁴ The majority of these reconstructions maintain long-term structural integrity. However, between 1.7% and 9.4% will need to undergo revision ACLR.⁵ Recent studies have even shown failure up to 23% in patients younger than 25 years after returning to sport.⁶ Failure can result from multiple causes, including technical failures from improper tunnel position. Revision ACLR can be technically more challenging due to the need to address bone loss or voids as a result of malpositioned tunnels, resultant defects when metal screws require removal, or properly positioned tunnels that have expanded significantly beyond their original diameter.

Currently, there are 2 options for revision ACLR when there is a need to address malpositioned,

significantly dilated tunnels or simply bone voids that may interfere with achieving a successful revision reconstruction: a single-stage combined procedure or a 2-stage approach in which the bone tunnels are grafted during the initial procedure followed by the subsequent revision ACLR typically 3 to 6 months after the graft has healed. Factors that affect decision-making are multifactorial and include previous tunnel position, tunnel diameter, revision graft choice and fixation method, possible concomitant procedures, and surgeon discretion. Ultimately, what is critical is the ability to successfully place and fixate a revision graft into a desired position with adequate biomechanical stability until it can successfully heal in a viable biologic environment without significant compromise.

Traditionally, tunnels expanded to greater than 12 to 15 mm in diameter or malpositioned tunnels, which will likely interfere with proper tunnel placement or fixation integrity, have been addressed using a 2-stage approach.⁴ This includes initial bone grafting of previous tunnel(s) with autograft, allograft, or bone graft substitutes (BGS), followed by delayed ligament reconstruction after the graft has adequately incorporated.⁵ Two-stage techniques are less optimal due to increased convalescence of 2 separate staged procedures, longer overall rehabilitation time and return to activity, increased cost, and financial implications stemming from time away from work or school.

Various techniques have been described and used over the years to achieve the goal of converting 2-stage revisions into successful single-stage revisions without

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compromising the ultimate outcome.⁵ Metal or bio-absorbable screws may be “stacked” adjacent to one another in order to fill a bone void and provide rigid stability to a graft in a revision setting.³ Sgaglione and Douglas⁷ described a technique for a single-stage procedure in which corticocancellous allograft strips were inserted into a widened tibial tunnel to “shim” the bone block and provide fixation for the bone block. Bio-absorbable or biocomposite interference screws may be placed into malpositioned tunnels or voids, which can subsequently be partially reamed to create a new tunnel adjacent or overlapping to the first. Metal screws, which may interfere, also can be replaced with these screws and reamed without generating metal debris. If using an allograft for the revision graft, large bone plugs may be maintained to fill larger defects or tunnels. Recently, Werner et al.⁵ described a new single-stage conversion technique that uses allograft bone dowels to fill malpositioned tunnels or bone defects. However, this novel technique may be more technically demanding for some surgeons. Other investigators have described various additional techniques for potentially converting to a single-stage approach with the use of BGS.^{5,8,9} However, a paucity of literature exists about the use of BGS in single-stage revision ACLR *in vivo*.

There are approximately 2.2 million bone graft procedures performed each year around the world to repair bone defects in orthopaedics, neurosurgery, and oral and maxillofacial surgery. Traditionally, BGS have been used in the setting of fracture repair and fixation to avoid donor-site morbidity associated with autograft.⁹ Fast-setting BGS have been used successfully for the last 20 years to provide structural support in the fixation of periarticular fractures including one of the more common indications tibial plateau fractures.⁹ Although remodeling and resorption time is controversial and may take many years if ever at all, there have not been reports of significant long-term problems due to failure of structural integrity over time. In addition, successful results without delayed structural failure has been reported in the treatment of aneurysmal bone cysts following curettage.¹⁰ These compounds have been shown to have 4 to 10 times the compressive strength of cancellous bone grafts, which allows them to enhance structural stability as well as to improve fixation when screws are placed through the hardened graft substitutes.¹¹

Vaughn et al.¹¹ described using fast-setting calcium phosphate BGS in simulated single-stage revision ACLR on cadavers with promising results. They showed *in vitro* that a BGS can effectively be used to fill bone defects without sacrificing tunnel position or compromising immediate graft fixation strength.¹¹ A follow-up study by Tse et al.¹² subjected the fast-setting calcium phosphate BGS to cyclical loading to simulate 2 months of walking, concluding this method was

biomechanically sound. Yamaguchi et al.¹³ recently described the use of BGS in the 2-stage revision setting, noting the fact that existing tunnels often have an irregular shape and the malleable BGS may be more optimal to fill these defects compared to bone dowels or other structural allografts. Nonstructural allograft or autograft may achieve this same goal, but a 2-stage revision is typically required since they do not provide immediate structural support. In this article, we present a novel single-stage approach to filling malpositioned and/or large bone voids using quick-setting bone graft substitutes, which can be implanted arthroscopically in an aqueous environment. We have used this technique successfully for cases that we would often have previously addressed using a 2-stage approach or in a single-stage procedure instead of one of the alternative techniques previously described. We have found this technique to often be much easier, structurally stable, and expeditious during revision surgery relative to other techniques.

Technique

BGS Material

We have used 4 different commercially available fast-setting BGS over the past 6 years. All of these are essentially composed of calcium phosphate with various additives (Montage: Abyrx, Irvington, NY; Equivabone, Etex: Zimmer/Biomet, Warsaw, IN; Gamma-BSM Moldable Putty, Zimmer/Biomet; and Beta BSM Injectable, Zimmer/Biomet) (Table 1). Each product is formulated to potentially set within a matter of minutes in a nonaqueous environment. Each can also be potentially used in an aqueous environment as well; however, we have found significant differences in the handling characteristics and solidifying properties in this setting. We found all of the products to work quite well in a dry environment (i.e., dry tibial tunnel), but the more hydrophilic products were not as stable in an aqueous environment and much more difficult to successfully deliver and manipulate to the desired shape within a void. One of the BGS, which is composed of calcium phosphate, resorbable polymer, and vitamin E acetate, results in a composition that we have found to be nongranular, cohesive (polymer adds cohesiveness), and hydrophobic (property of vitamin E). The cohesiveness and viscosity resist bulk fluid penetration and the hydrophobic nature resists fluid absorption. These properties within the arthroscopic environment are desirable in that it allows stability and hardening within bone voids without the need for a dry environment. A key feature is that this specific BGS avoided displacement and dissolution during insertion and while hardening within the aqueous environment, a problem we ran into with some of the other BGS in this setting. For a single-stage revision ACL reconstruction

Table 1. Different BGS and Their Properties That Were Used in Our Technique

Substance	Montage Abyrx	Equivabone Zimmer/Biomet*	Gamma-BSM Moldable Putty Zimmer/Biomet	Beta-BSM Injectable Zimmer/Biomet
Setting time	Within minutes	Endothermically sets in 10 minutes at 37°C	Endothermically sets in 3-5 minutes at 37°C	Endothermically sets in 3-5 minutes at 37°C
Composition	Granular CaP, calcium stearate, vitamin E acetate, a triglyceride, a polyalcohol and a mixture of lactide diester and polyester-based polymers	Synthetic calcium phosphate, carboxymethyl cellulose + demineralized bone matrix	Proprietary nanocrystalline CaP	Proprietary nanocrystalline CaP
Remodeling	CaP is resorbed during bone remodeling (>30 days)	Inductive DBM promotes bone formation, CaP remodels at the rate of new bone growth. Cell-mediated	Remodels at the rate of new bone growth. Cell-mediated.	Remodels at the rate of new bone growth. Cell-mediated.
Compressive strength	Between cancellous and cortical bone (no numerical value reported)	1-2 MPa	46 MPa	30 MPa

BGS, bone graft substitute; CaP, calcium phosphate; DBM, demineralized bone matrix.

*Zimmer/Biomet products produced by Etex (Cambridge, MA).

to be done in an expeditious manner, it is advantageous to use a material that will be stable in the aqueous environment during injection and placement, yet harden quickly so that a new tunnel can be drilled into the material if required. The various quick setting BGS products the authors have used for revision ACL reconstruction can be seen in [Table 1](#).

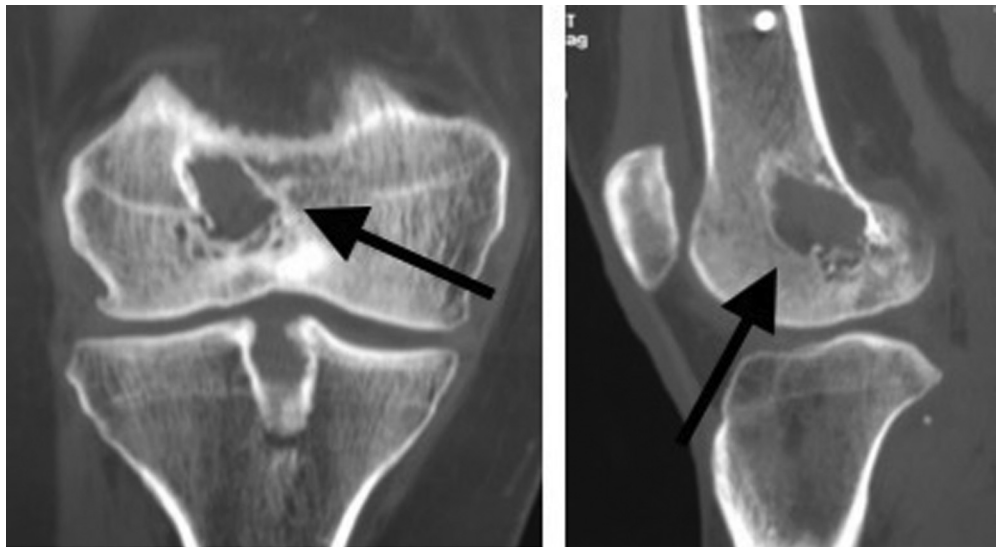
Surgical Technique (With Video Illustration)

Each patient requires a unique operative strategy due to previously implanted hardware, graft selection, and tunnel status. Preoperative imaging, often including computed tomography, is used to assess tunnel position, size, and previous fixation hardware ([Fig 1](#)), as well as to determine planned position of revision tunnels relative to previous tunnels. Basically, the

feasibility of success of a single versus 2-stage approach must be assessed on a case-by-case basis.

The initial step is to typically remove previous hardware that may interfere with the revision procedure and to debride and remove any soft tissue in the previous ACL tunnels that will be subsequently grafted ([Video 1](#)). Next, the fast-setting BGS product is prepared based on commercial instructions and placed into an arthroscopic delivery device. On the femoral side, a number of different devices can be used to deliver the BGS into the tunnel arthroscopically. We have found the most optimal delivery device is a long clear cannula (Etex; Zimmer/Biomet), which can be used to deliver the graft substitute into the femoral tunnel. We have also used instruments from an arthroscopic autograft transfer system, Osteochondral Autograft Transfer

Fig 1. Preoperative anteroposterior and lateral knee computed tomography of right knee showing large, wide femoral tunnel (arrow)



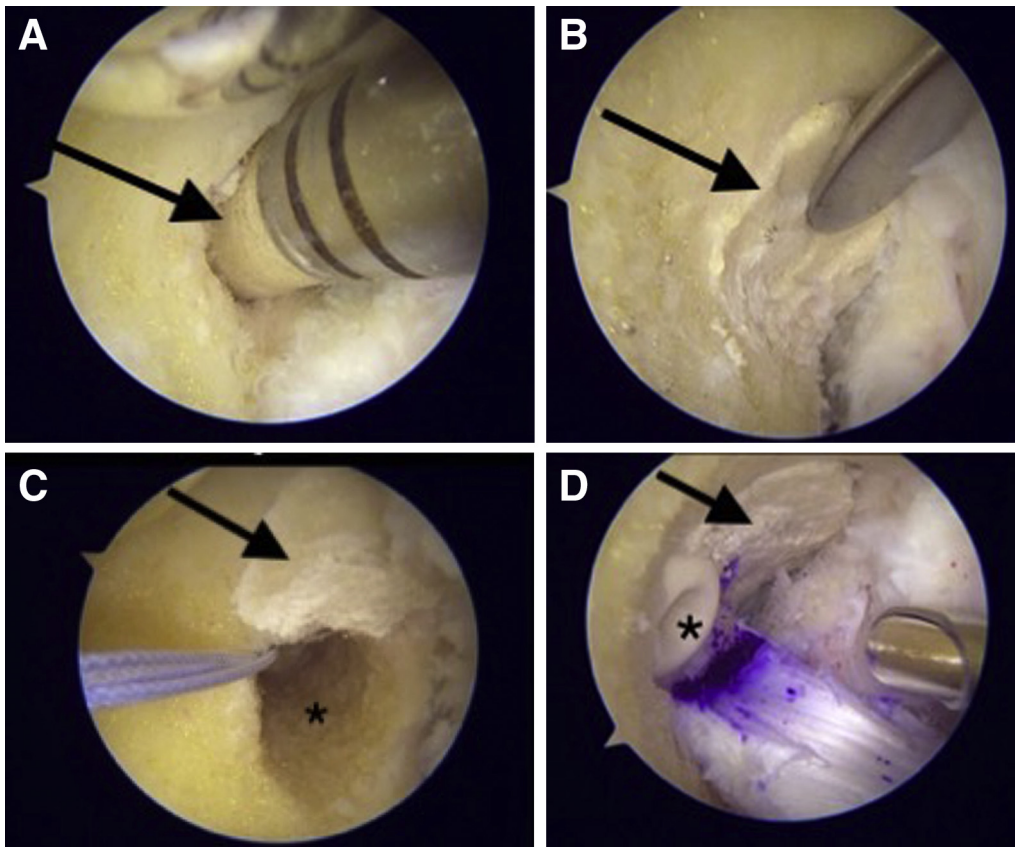


Fig 2. (A) Arthroscopic view of the right knee from the commercially available cannula inserted through anteromedial portal and the bone graft substitute being injected into previous femoral tunnel (arrow). (B) Arthroscopic view of right knee showing arthroscopic instrument contouring and tamping BGS in previous femoral tunnel (arrow). (C) Arthroscopic view of right knee showing newly drilled femoral tunnel (asterisk) in the correct anatomic position with the BGS filling the previous tunnel (arrow). (D) Arthroscopic view of right knee showing hardened BGS (arrow) and final revision in place with graft and interference screw (asterisk). (BGS, bone graft substitutes.)

System (OATS) by (Arthrex, Naples, FL). New instrumentation is currently in development for optimizing arthroscopic femoral tunnel or void delivery. The amount of BGS will vary based on the defect volume. The delivery device is typically placed thru the anteromedial portal to obtain optimal access to the femoral tunnel. Once placed into the tunnel, the BGS is injected arthroscopically while directly visualizing appropriate fill into the tunnel. The BGS is impacted and contoured to the native lateral wall using arthroscopic instruments and then allowed to harden (Fig 2).

In most cases, the delivery system is placed through an anteromedial portal. Alternatively, a malpositioned or dilated femoral tunnel may be more accessible to grafting thru a prepared tibial tunnel if the primary femoral tunnel was drilled via a transtibial method. However, we generally prefer the anteromedial portal approach. On the tibial side, once any remaining soft tissue from the previous graft material is debrided out of the tunnel, the BGS product is injected into the tibial tunnel with the scope in the joint. A spatula-type device is arthroscopically placed above the tibial tunnel to avoid injecting the graft into the joint (Fig 2).

Delivery devices are used to push or inject the putty-like material into the tunnel and tamp the material into the bone voids. The BGS is contoured to make it flush with the overlying bone using various arthroscopic instruments, including curettes, impaction instruments, and freer-type instruments. Once the BGS is hardened, we drill new tunnels in the desired anatomic position as you would in a staged revision (Fig 2). We have found all of the quick-setting BGS take longer to harden or not completely harden at the setting times reported by grafts respective manufacturers. However, most are hardened with enough structural integrity by 20 minutes following placement. We have not found an issue with drilling into the bone graft material once hardened. Similar to bone, we make sure to remove graft debris generated from the reaming process. Graft placement and fixation is similar to standard revision ACLR procedures. We have not found an issue with placing interference screws into the BGS material once hardened. We have not seen any failures of fixation at “time zero” at the time of interference screw fixation or with follow-up thus far. The pearls and pitfalls of this procedure are outlined in Table 2.

Table 2. Pearls and Pitfalls of ACL Revision Using Fast-Setting BGS

Pearls	Pitfalls
Debride residual soft tissue from previous tunnel	Graft failure
Choose appropriate BGS based on surgeon preference and properties	Inadequate healing due ratio of BGS to native bone being too high
Allow adequate time for BGS hardening	Improper tunnel positioning

ACL, anterior cruciate ligament; BGS, bone graft substitute.

Discussion

Revision ACLR with bone defects or voids from previous procedures can be problematic and has not uncommonly necessitated a 2-staged approach to address bone voids that would complicate or compromise a single-stage revision. We do not hesitate to perform a 2-staged revision if needed. However, using a technique that eliminates the necessity of a 2-stage approach without compromising outcome success in certain settings is clearly advantageous. Benefits include fewer operative procedures, more rapid overall recovery time, decreased convalescence time, and cost effectiveness. The technique described in this article has been performed in an effort to convert a percentage of revision procedures from 2-stage to a single-stage revision or to just make single-stage procedures more straightforward.

A number of other techniques have been described that attempt to achieve the same goal.⁵ These include stacked screws, maintenance of large plugs on an allograft, use of biocomposite screws as void fillers, and structural allografts in the form of match sticks or more recently preshaped dowels.^{3,5,8,9} We have used a number of these techniques in the past but sometimes they can come with technical challenges, especially when dealing with large irregular or misshaped bone voids. This situation is where we have found the use of these malleable quick setting BGS to be most useful. They are able to be used to permeate into irregular voids with a fairly straightforward technique and provide structural integrity which can support successful graft fixation, rehabilitation and recovery. We have essentially used Vaughn et al.'s initial study concept to show that their original cadaver studies can be applied successfully in vivo. Our rationale was also based on the

long-successful experience with the use of these BGS for other orthopaedic indications, such as fracture fixation and healing. We have up to almost 6-year follow-up when used in the revision setting and have not had any complications or revisions thus far. We did change our preferred BGS several years ago as the result of our experience with delivery and utilization within an aqueous arthroscopic environment.

The optimal BGS for this situation is one that is initially pliable to allow for easy delivery, remains stable and hardens quickly in an aqueous environment, and allows for the revision to be performed in one operation successfully. We have encountered that the grafts can take longer to set than reported by manufacturers and it is important to let the BGS set before reaming into it. We have not had any issues with the grafts being too hard to drill into after they harden.

As previously stated, we still feel there are situations in which a staged approach is certainly prudent. One very important issue to consider is successful biological healing of the graft within a revision tunnel. A graft will not heal within an avascular tunnel no matter if created within allograft or a BGS. A viable biologic interface between the revision graft and tunnels is critical for healing and ultimate success. It is unknown the circumferential percentage of the tunnel that needs to be viable bone to support successful incorporation and healing. There are several factors that may affect successful graft healing in this setting, which is beyond the scope of this article. However, this situation also exists for other revision scenarios as well where grafts are placed adjacent to screws or structural allografts. This technique has been used by the authors so that a majority of the circumference of the new tunnel is native viable bone hopefully allowing for successful graft

Table 3. Advantages and Disadvantages of ACL Revision Using Fast-Setting BGS

Advantages	Disadvantages
May eliminate the need for 2-staged procedures in select cases	Limited long-term follow-up
More straightforward than other options to fill bone voids or expanded tunnels	Possibility of BGS mechanical failure during remodeling
No risk of disease transmission vs allograft tissue	May take a long time to remodel or it may never remodel into viable bone
Decreased surgical time	
No donor-site morbidity	

ACL, anterior cruciate ligament; BGS, bone graft substitute.

healing. Thus, if a new tunnel will be primarily within the nonviable BGS, we would opt for a staged revision using structural or nonstructural allograft versus cancellous autograft bone. These grafts are avascular and will take time to incorporate and remodel.⁹

The Food and Drug Administration approved the use of calcium sulfate and calcium phosphate to be used within BGS in 1996. Now, there are numerous types and formulations of bone graft substitutes, each with different materials and properties. Due to these differences, each bone graft needs to be specifically chosen for its intended use.¹⁴ BGSs can remodel via osteogenesis, osteoinduction, and/or osteoconduction, although it is controversial how long this takes and if this truly occurs in all materials. The products we used were all calcium phosphate based, which is osteoconductive and bioresorbable. Calcium phosphate has been shown to have a compressive strength of up to 4 to 10 greater than cancellous bone. Typically, these properties allow for early weight bearing and immediate construct stability with this revision technique when used for bone defects on either the femoral or tibial side. We have been more comfortable with the immediate and delayed structural integrity of these constructs based on the work of Vaughn et al., who showed stable constructs at time zero in a cadaver model as well as follow-up studies showing success with the use of quick-setting calcium phosphate in open reduction and internal fixation of depressed tibial plateau fractures.^{11,15} In our experience thus far, our patients' revision constructs have maintained their structural integrity without graft or fixation failure.

Although we have not encountered any issues with this technique, there are some theoretical risks involved in using BGS during revision procedures. As we mentioned earlier, there is risk that the BGS will not incorporate due to its avascular nature, which could ultimately lead to failure of the ACL graft. Similar to structural allografts there is always the risk of delayed failure due to mechanical compromise during the remodeling process. We have fortunately not encountered any problems related to this issue of date. Another risk and/or limitation to be considered is the surgeon's estimation on how much of the circumference of the new tunnel will be avascular BGS versus native bone. We currently do not have an absolute recommendation but typically would recommend at least 50% of the circumference in the new tunnel to be viable native bone. Similar to other ACL revision techniques, this issue should be thoughtfully considered. Ultimately, the surgeon needs to assess on a case-by-case basis the likelihood of success of the revision graft healing within a new tunnel with adequate structural support while the graft heals to viable bone. A summary of these advantages and disadvantages are listed in Table 3.

There are clear benefits to single-stage versus 2-stage revision ACLR if it can be performed without compromising the ultimate outcome. This technique may be a potential addition to the armamentarium of the ACL surgeon so as to convert a percentage of revisions that would have been done through a 2-staged approach to a single-staged procedure. In addition, surgeons may just find the technique less challenging to address bone voids than other single-stage revision options. Although we have not seen complications or problems with this technique in the relatively short-term it will be important to obtain longer-term follow-up.

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