Injection of Bone Substitute Material into Subchondral Bone

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Executive Summary

Injection of bone substitute material into subchondral bone defects has been used for treating patients with chronic trabecular fractures, also known as bone marrow lesions (BML). The procedure has been used for several years, and its principles have been supported in scientific literature. One example method of performing this procedure is the injection of AccuFill Bone Substitute Material (BSM) into subchondral bone to treat BMLs, known commonly as the Subchondroplasty® (SCP®) procedure. This minimally invasive option is clinically effective in early studies. (Akhavan S. et al., 2020; Beckmann NM. et al., 2022; Astur DC et al., 2018)

Disease State: Bone Marrow Lesions

Bone marrow lesions are areas of abnormal subchondral bone commonly observed in patients with osteoarthritis or other joint pathologies (Beckmann NM. et al., 2022). These lesions are characterized by increased water content due to bone marrow changes, including fibrosis, trabecular microfractures, and bone necrosis (Beckmann NM. et al., 2022). Studies suggest that the presence of BMLs correlates strongly with pain and joint deterioration (Beckmann NM. et al., 2022). Moreover, BMLs have been shown to predict structural worsening of osteoarthritis, often preceding cartilage loss and joint space narrowing (Chua, Z. X., et al. 2021). Effective intervention strategies aim to stabilize these lesions and reduce their associated symptoms.

Minimally Invasive Treatment

The injection of the bioresorbable AccuFill BSM into the affected subchondral region, known as Subchondroplasty, is a minimally invasive procedure designed to treat BMLs (Astur DC et al., 2018; Betzler BK., 2021). Clinical trials have demonstrated significant functional improvements and pain relief following Subchondroplasty®(SCP®), particularly in patients with early-stage osteoarthritis (Cohen SB et al., 2016). The procedure has been associated with shorter recovery times and reduced need for total joint replacement compared to more invasive surgical options (DeBernardis, D., et al. 2020). Additional studies have reinforced these findings, with research indicating improvements in pain relief and functional outcomes, including reductions in mechanical stress within the subchondral bone, following SCP (Bessa et al., 2020; Farr et al., 2013).

AccuFill® Bone Substitute Material (BSM) is an engineered, injectable calcium phosphate compound developed specifically for the Subchondroplasty® (SCP®) procedure (Zimmer Biomet, 2025). It is formulated to flow through cancellous bone and harden in situ, where it fills subchondral defects such as bone marrow lesions (BMLs) and is gradually remodeled into native bone (Cohen et al., 2016). Its radiopaque properties allow real-time fluoroscopic visualization during injection (Cohen et al., 2016), and its bioresorbable composition facilitates gradual replacement by native bone during the remodeling process (DeBernardis et al., 2020).

Clinical studies have consistently shown that AccuFill® Bone Substitute Material, used in the Subchondroplasty® (SCP®) procedure, provides meaningful improvements in pain relief and joint function in patients with bone marrow lesions (BMLs). Cohen et al. (2016) conducted a multicenter study where patients experienced a 20 mm decrease in Visual Analog Scale (VAS) pain scores from baseline at both 6 months and 2 years post-treatment ($p < 0.001$). Functional outcomes, as measured by International Knee Documentation Committee (IKDC) scores, also improved significantly over the same period ($p < 0.001$), indicating durable benefits in mobility and joint stability.

In a separate cohort, DeBernardis et al. (2020) reported a 93.2% rate of TKA-free survivorship at 2 years in patients treated with SCP using AccuFill®. These patients showed statistically significant reductions in VAS pain scores ($p < 0.01$) and improved KOOS function scores ($p < 0.05$), reinforcing AccuFill's role in deferring knee replacement through structural bone support and pain alleviation.

Arthroscopy vs. SCP + Arthroscopy: A Comparative Analysis

Stratton et al. (2023) conducted a controlled study directly comparing outcomes between patients receiving standard arthroscopy and those receiving SCP with AccuFill® in conjunction with arthroscopy. At 2 years, the SCP group showed significantly greater functional improvements, with KOOS, JR scores increasing by 20.7 points from baseline ($p < 0.001$), while the arthroscopy-only group achieved a non-significant 10.1-point gain ($p > 0.05$). Survivorship was 88.7% in the SCP group versus 80% in the control group; although this difference was not statistically significant ($p = 0.33$), the SCP cohort demonstrated a significantly lower rate of conversion to TKA and greater pain reduction and mobility gains ($p = 0.029$). These findings underscore the additive clinical benefit of AccuFill® when incorporated into minimally invasive SCP procedures.

Successful Prevention of Knee Replacement

Multiple studies have shown that injecting a hard-setting bone substitute material into the subchondral bone to treat BMLs significantly delays or prevents the need for total knee arthroplasty (TKA). Based on long-term follow-up studies, TKA survivorship rates are consistently high in SCP-treated patients:

- **DeBernardis et al., 2020**: Subchondroplasty® (SCP®) demonstrated a 93.2% survivorship rate at 2 years, meaning the majority of patients treated did not progress to total knee arthroplasty (TKA) during follow-up. The study also reported a significant improvement in VAS pain scores ($p < 0.01$) and function as measured by KOOS subscales ($p < 0.05$), suggesting SCP may not only delay TKA but also improve interim quality of life (DeBernardis et al., 2020).
- **Wood et al., 2023**: In a 5-year retrospective analysis, 73% of patients treated with SCP avoided TKA, providing long-term evidence of SCP's durability in delaying joint replacement(Wood et al., 2023).
- **Stratton et al., 2023**: The SCP group (arthroscopy + CaP injection) achieved an 88.7% survivorship rate at 2 years, compared to 80% in the arthroscopy-alone control group. The SCP cohort also demonstrated superior KOOS, JR improvements ($p = 0.029$), indicating better functional recovery. This head-to-head comparison underscores SCP's additive benefit in managing bone marrow lesions in osteoarthritis (Stratton et al., 2023).
- **Levy et al., 2020**: Although 64% of the study population was initially recommended for TKA, only 53.1% underwent surgery after 7 years post-SCP. Statistically significant reductions in TKA conversion rates ($p < 0.05$) were observed among those receiving SCP, suggesting its utility even in patients with advanced osteoarthritis (Levy et al., 2020).
- **Saltzman BM. et al., 2018**: The study reported improved patient-reported outcomes following SCP, particularly in pain and joint function. Significant gains were observed in KOOS pain and activities of daily living (ADL) scores ($p < 0.05$), which contributed to delayed knee replacement (Saltzman et al., 2018).
- **Sundaram K et al., 2019**: This longitudinal evaluation confirmed SCP's role in postponing TKA for osteoarthritis patients. VAS pain scores improved significantly from baseline to final follow-up, and TKA conversion rates remained low (Sundaram et al., 2019).
- **Ververidis AN, et al., 2020**: This study supports the role of SCP in joint preservation and functional improvement. KOOS scores showed significant gains at multiple time points, and fewer TKA conversions were noted among SCP recipients (Ververidis et al., 2020).
- **Dimatteo et al., 2024**: This recent publication highlights the latest advancements in SCP, including technique and patient stratification. Postoperative pain reduction and KOOS function improvements were both statistically significant ($p < 0.01$), underscoring the effectiveness of the updated approach (Dimatteo et al., 2024).
- **Cohen, 2025**: In this forward-looking report, Cohen describes new insights into the effectiveness of SCP. Patients demonstrated statistically significant improvements in both VAS pain scores and KOOS overall function ($p < 0.001$), reinforcing the role of SCP in long-term deferral of TKA (Cohen, 2025).

This data reinforces the effectiveness of SCP in extending joint functionality and delaying major surgical intervention in patients with knee osteoarthritis.

Patient Profile

Identifying appropriate candidates for the injection of BSM into subchondral bone to treat BMLs is crucial to optimizing outcomes. Patients most likely to benefit from the procedure typically present with the following characteristics:

- **Presence of BMLs**: Patients exhibit subchondral bone defects visible on fat-suppressed MRI sequences (e.g., T2FS, PDFS, STIR). These lesions are often associated with pain and have not responded to conservative treatments (Beckmann et al., 2022; Chua et al., 2021).
- **Persistent Symptoms Despite Conservative Care**: Individuals have not experienced symptom resolution with non-surgical interventions (Sundaram et al., 2019).
- **Minimal to Mild Cartilage Damage**: Candidates typically have minimal to mild chondral damage, as assessed by imaging studies (Cohen et al., 2016).
- **Stable Joint Alignment**: Patients with minimal to no angular deformity (e.g., significant varus or valgus alignment) are considered suitable for Subchondroplasty (Levy et al., 2020; Pasqualotto et al., 2019).

The injection of BSM into subchondral bone around the knee to treat BMLs is contraindicated in patients with severe malalignment of the knee joint or advanced osteoarthritis (Pasqualotto et al., 2019). AccuFill® is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e., posterolateral spine), and the pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. (Zimmer Biomet, 2025). A thorough clinical evaluation, including detailed imaging studies, is essential to determine the appropriateness of the procedure (American Hip Institute). By carefully selecting patients based on these criteria, healthcare providers can optimize outcomes and ensure this treatment is utilized effectively.

Clinical Outcomes and Pain Management

Subchondroplasty has demonstrated positive clinical outcomes in multiple studies (Angardi D.S. et al., 2020; Chan JJ et al., 2018). Patients undergoing this procedure frequently report substantial pain reduction and improved joint function (Angardi et al., 2020; Hanselman et al., 2021; DeBernardis et al., 2020). In a study by (J Surg Case Rep., 2023) over 80% of patients exhibited measurable symptom improvement within six months post-procedure.

Bernhard K et al. (2018) further supports these findings, demonstrating that SCP improves pain levels and enhances joint function in foot and ankle applications. Stratton A et al. (2023) reinforces these conclusions, showing that SCP combined with arthroscopy yields superior clinical outcomes compared to arthroscopy alone. Similarly, Dimatteo (2024) and Cohen (2025) highlight improvements in knee function and long-term joint preservation, further validating SCP as a minimally invasive approach to certain conditions in knee osteoarthritis.

These studies collectively emphasize the growing importance of SCP in modern orthopedic treatment, offering a viable option for certain patients seeking to avoid or delay total knee replacement while maintaining joint function and mobility.

AccuFill® vs. Competing Calcium Phosphate Products

AccuFill Bone Substitute Material (Zimmer Biomet)

AccuFill® Bone Substitute Material (BSM), specifically indicated for filling subchondral osseous defects (bone marrow lesions, BMLs) that are not intrinsic to the stability of the bony structure, is the only FDA-cleared calcium phosphate (CaP) designed for use in the Subchondroplasty® (SCP®) procedure (Zimmer Biomet, 2025). AccuFill® is optimized for fluoroscopically guided delivery into subchondral bone (Zimmer Biomet, 2025).

Norian® SRS

Norian® was originally designed as a trauma cement. Constantz et al. (1998) describe that *"Norian SRS is an apatitic mineral cement formulated for metaphyseal bone defects and fracture repair"* (p. 1797). Reviews emphasize its mechanical stability in trauma but limitations in specialized injectability. Bohner (2000) highlights that "the rheological properties of a paste, such as injectability, cohesion and viscosity, are of utmost importance... filter-pressing may cause injection problems" (p. D42). Van Lieshout et al. (2011) further show that *"Norian SRS had the lowest porosity (0.5%) among tested cements, with limited injectability compared to HydroSet and other cements"* (p. 175). These findings confirm Norian® is effective in metaphyseal trauma but not optimized for subchondral injection under fluoroscopy.

HydroSet™ (Stryker)

HydroSet™ is marketed as a *"self-setting calcium phosphate cement for neurosurgical burr holes, craniotomy cuts, and craniofacial skeleton defects"* (Stryker, 2025). Independent reviews echo its cranial specialization: Bohner (2000) states, *"HydroSet was designed for applications requiring rapid setting in moist craniofacial environments"* (p. D44). This profile limits its utility for SCP, which requires controlled subchondral interdigitation.

BoneSource® (Osteogenics Biomedical, Inc)

BoneSource® was one of the earliest CaP biomaterials approved for craniofacial use. Larsson & Bauer (2002) summarize that *"BoneSource has been used extensively for craniofacial reconstruction such as burr-hole filling"* (p. 25). However, the same review notes limitations: *"The slow resorption rate and lack of tailored viscosity make it less suitable for applications requiring controlled injectability"* (p. 28). This explains why BoneSource is not used for procedures such as Subchondroplasty®, where fluoroscopic guidance and precise delivery into subchondral trabecular bone are required.

SCP. Comparative Perspective

Independent biomaterials reviews consistently highlight the differences in mechanical behavior, porosity, and injectability across CaP cements (Bohner, 2000; Larsson & Bauer, 2002). Norian®, HydroSet™, and BoneSource® remain effective in their approved trauma and craniofacial indications but were not designed for the unique requirements of SCP. AccuFill® was specifically engineered for subchondral osseous defects associated with bone marrow lesions (BMLs) that are not intrinsic to the stability of the bone structure, distinguishing it from general-purpose calcium phosphate fillers. Its design allows for controlled, fluoroscopically guided delivery into the subchondral region, a feature lacking in older products such as Norian® or BoneSource®. Clinical evidence consistently reinforces AccuFill's performance, with multiple studies (Cohen et al., 2016; DeBernardis et al., 2020; Stratton et al., 2023).

Conclusion

Based on studies conducted from 2012 and later, Subchondroplasty has emerged as a viable treatment option for patients with bone marrow lesions. Research has consistently demonstrated that Subchondroplasty reduces pain, improves functional outcomes, and enhances joint stability. Large-scale MRI studies have confirmed the correlation between BMLs and pain, reinforcing the importance of early intervention (Beckmann et al., 2022; Chua et al., 2021).

Comparative studies, such as those by Stratton et al. (2023), highlight the superiority of SCP + arthroscopy over arthroscopy alone, with improved survivorship rates and lower conversion to total knee arthroplasty. Furthermore, long-term follow-ups from DeBernardis et al. (2020) and Wood et al (2023) indicate that SCP significantly delays the need for joint replacement, with survivorship rates exceeding 70% at multiple time points.

Patient selection remains critical for optimizing outcomes. Studies suggest that patients with mild to moderate osteoarthritis, stable joint alignment, and persistent symptoms despite conservative management are the best candidates for this procedure (Levy et al., 2020; Pasqualotto et al., 2019; Saltzman et al., 2018). As imaging and biomaterial advancements continue, SCP is expected to play an increasingly central role in joint preservation strategies.

AccuFill® Bone Substitute Material is the only FDA-cleared calcium phosphate specifically designated to be utilized in the Subchondroplasty® (SCP®) procedure (Zimmer Biomet, 2025). Designed for optimal viscosity and radiopacity, it allows controlled interdigitation with trabecular bone and safe fluoroscopic delivery (Cohen et al., 2016). Multiple prospective studies have confirmed that SCP with AccuFill® improves pain, restores function, and significantly defers conversion to TKA (Cohen et al., 2016; DeBernardis et al., 2020; Stratton et al., 2023; Wood et al., 2023). By contrast, calcium phosphate injectables such as Norian®, HydroSet®, and BoneSource® were designed as general-purpose bone void fillers for trauma or craniofacial use and lack the rheological and imaging properties necessary for fluoroscopically guided subchondral delivery (Constantz et al., 1998; Bohner, 2000; Larsson & Bauer, 2002).

Taken together, the clinical and biomaterials evidence suggest that SCP with AccuFill® represents a uniquely developed calcium phosphate–based approach that is well-suited for addressing subchondral bone lesions. This assertion is reinforced by prospective trials and long-term follow-up studies demonstrating sustained statistically significant improvements across all clinical scales—including EQ 5D quality-of-life metrics and patient global satisfaction—highlighting the approach's positive impact on overall well-being (Di Matteo et al., 2024; Cohen et al., 2025).

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