

Emerging Options Using Osteobiologics Treatment for FFP Type IA Comminuted Stable Fragility Fractures Involving the Pubic Rami

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Received: 20 Aug 2022; Accepted: 19 Sep 2022; Published: 25 Sep 2022

Citation: Ray JM. Emerging Options Using Osteobiologics Treatment for FFP Type IA Comminuted Stable Fragility Fractures Involving the Pubic Rami. J Med - Clin Res & Rev. 2022; 6(9): 1-7.

ABSTRACT

Introduction: For many elderly patients who sustain a pubic rami fracture after a fall, the traditional treatment of extended bed rest and restricted mobility is often not practical. A classification for pubic rami fractures has been developed to recommend treatment. There is a technique to augment the biologic fracture environment using Calcium Phosphate through a minimally invasive procedure. In this study FFP Type Ia fractures were treated using Calcium phosphate.

Methods: Our study, from January 1, 2018, to December 31, 2019, identified eighty-eight patients with FFP Type Ia fractures, who were treated with Calcium Phosphate. There were 9 males and 79 females, average ages were 78 and 86 respectively. Admission workup included pelvic x-rays as well as a CT scan. All received Calcium Phosphate for fracture fixation. They were followed in the outpatient clinic with pelvic radiographs at 3 weeks, 6 weeks, 6 months, 9 months and 1 year. Evidence of incorporation of the Calcium Phosphate in the fracture healing were documented.

Results: There were no infections, no vascular, and no urological complications with this technique. All treated fractures went on to heal. Incorporation of the Calcium Phosphate was noted as early as 12 weeks. Residual presence of Calcium Phosphate was seen at 1 year and was consistent with the research literature.

Conclusion: This new method of minimally invasive internal fixation using a bone biologic enhancement material provides an immediate improvement of post injury pain and an increase in immediate post treatment mobility. This treatment is applicable for all pelvic fragility fractures, including Type Ia who present with comminution. Risks with this treatment are low and benefits to the patient are high.

Keywords

Pubic rami fractures, Calcium Phosphate, Fragility Fractures, Classification Type Ia.

Introduction

Fragility fractures of the pelvis are increasing in frequency in our elderly population. In most cases patients suffer a minor injury, have intense pain in the pelvic region and impaired mobility. The incidence of fragility fractures of the pelvis in the elderly is greatly increasing due to the rise in life expectancy and an

aging population [1-4]. The overall incidence rate of pubic ramus fractures in the United States between 2002 and 2019 was 13.47 per 1,000,000 people 60 years and older (95% confidence limit: 9.92-17.01). The incidence of pubic ramus fractures for females in the US was 21.71 (16.08-27.34) [5]. Epidemiological evidence suggests that the incidence of pelvic fragility fractures is on a global rise [6]. Due to the increasing incidence of osteoporosis-associated pelvic fractures, clinically important challenges are arising regarding diagnostic evaluation, fracture classification and treatment algorithms [7].

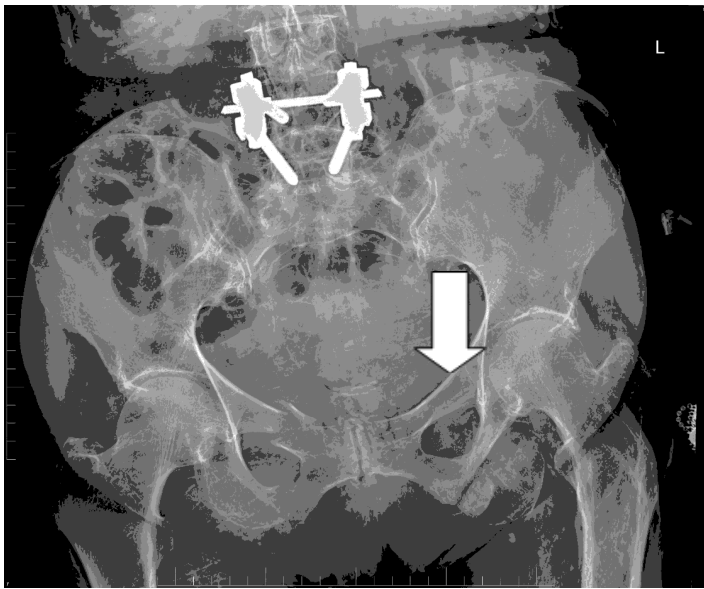


Figure 1: Comminuted pubic rami fracture AO/OTA Type A2.

Treatment goals should contain rapid pain relief and mobilization to avoid complications related to immobilization [8]. The leading symptom is immobilizing pain in the lower back, in the buttocks, in the inguinal region and/or at the pubic symphysis. The characteristics of these fractures are different from pelvic ring fractures in younger adults. Due to a specific and consistent decrease of bone mineral density, typical fractures in the anterior and posterior pelvic ring occur. Sacral ala fractures are common. A new understanding of modern strategies, for evaluating and treating fragility fractures of the pubic rami is paramount for maintaining their functional activities of daily living and preserving their independent quality of life.

The classification used initially to identify these fractures is of the Association for Osteosynthesis/Orthopedic Trauma Association (AO/OTA) developed by M. Tile [9]. This classification is difficult to apply to the pelvic fracture patterns in the elderly and may not reflect the true anatomic description of these fracture injuries. Currently there is no clinical studies to suggest treatment strategies for these fractures. A new classification was developed by Rommens, and Hofmann described as FFP (Fragility Fractures of the Pelvis) [10]. This new FFP classification system distinguishes between four categories with increasing loss of stability. For many elderly patients, the traditional treatment strategy of bed rest, narcotic pain control, and restricted mobility becomes impractical or unacceptable.

The primary goal of any treatment is restoring mobility and independency. The choice of the operation technique is dependent on the localization of the fracture. When a surgical treatment is chosen, the procedure should be as minimally invasive as possible. Rommens et al. proposed a classification system of four types. His study proposed FFP Type I lesions can be treated conservatively, FFP Types III and IV require surgical treatment. For FFP Type

II lesions, percutaneous fixation techniques should be considered after a trial of conservative treatment. FFP Type III lesions need open reduction and internal fixation, whereas FFP Type IV lesions require bilateral fixation. Surgical procedures such as open reduction and internal fixation or percutaneous intramedullary screw fixation have been suggested as the standard of care for chronic or severe displaced pubic rami fractures [11]. These procedures add to the surgical morbidity in management and prolong recovery. Even after treatment, patients reported long-lasting pain that had a severe effect on their daily routines, and many could not return to their normal status prior to injury [12].

The aim of the present study was to describe a new approach to surgical treatment for all patients sustaining fragility fractures of the pelvis regardless of the classification. This treatment protocol optimizes pain reduction and improved patient mobility. This procedure has been performed without the complications associated with other methods of fixation [13]. This treatment was performed on patients with FFP classification Ia. These fractures have been suggested to be treated conservatively. These patients have significant pain, limited mobility and would be restricted to prolonged bed rest until comfortable for ambulation and weightbearing.

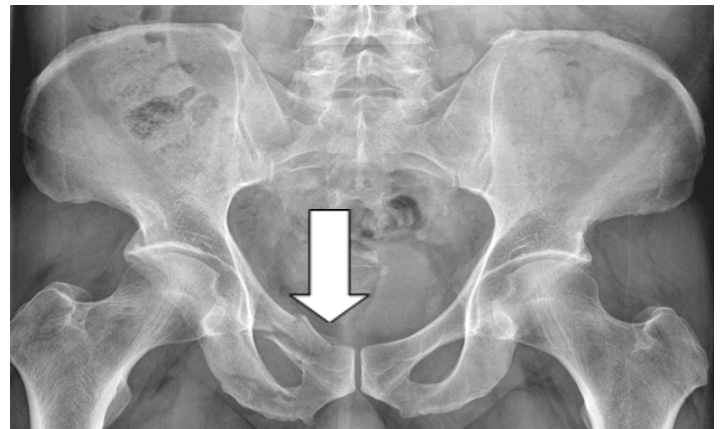


Figure 2: FFP Type Ia with minimal comminution.

Multiple biologic and mechanical factors influence a bone's ability to remodel as well as heal an acute fragility fracture of the pelvis. Osteobiologics is a term used to describe materials that have been identified and developed to promote bone healing. Calcium Phosphate is an Osteobiologics bone substitute recently developed to be applied as a treatment for insufficiency fractures by providing structural support to areas of decreased bone mineral density [14]. This substitute has recently been used successfully in the treatment of FFP Type Ia pubic rami fragility fractures in elderly patients. This procedure is performed by drilling into metaphyseal subcortical bone with a cannulated fluted guide pin. Under fluoroscopy, engineered Calcium Phosphate paste is injected into fracture defects forming a macro-porous scaffold for bone to increase the density and improve the structural integrity of cancellous bone [15]. The outcomes from treatment demonstrate fragility fracture healing with incorporation of the Calcium

Phosphate in the fracture repair. The healing of fractures with the incorporation of placed Calcium Phosphate has been demonstrated in the literature to occur at 4-6 weeks and completed by 1 year (16). The x-ray results of treated FFP Type Ia were followed to healing and were comparable to that reported in the literature.

Methods

From January 1, 2018, to December 31, 2019, our study identified 88 patients who sustained Fragility Fractures of the pubic rami. Eighty-seven patients were classified as Type Ia. There were 9 males and 78 females, average ages were 78 and 86 respectively. Pain on admission was rated as significant using the Visual Analog System, 0-10. All patients presented on admission with a 10/10 on the pain scale. On hospital admission, work-up included pelvic x-rays as well as a CT scan. The classification of the fractures was 87 FFP Type Ia.

After preop work-up the patients were taken to the operating room, and all received Calcium Phosphate for fracture fixation. Preoperative planning was conducted according to the fracture type and soft tissue condition. No patient was excluded, and all were taken to the operating room where under fluoroscopy control, cannulated trocars were inserted manually into the fracture sites. (Figure 3) The Calcium Phosphate was delivered, and the fractures were filled, and, in some cases, minimal extravasation was noted indicating the fracture site was full. (Figure 4) The injection sites were covered with Dermabond skin glue and an Opti foam bandage. No sutures were used. There was no bleeding encountered. The surgery was minimally invasive with bleeding recorded as minimal.

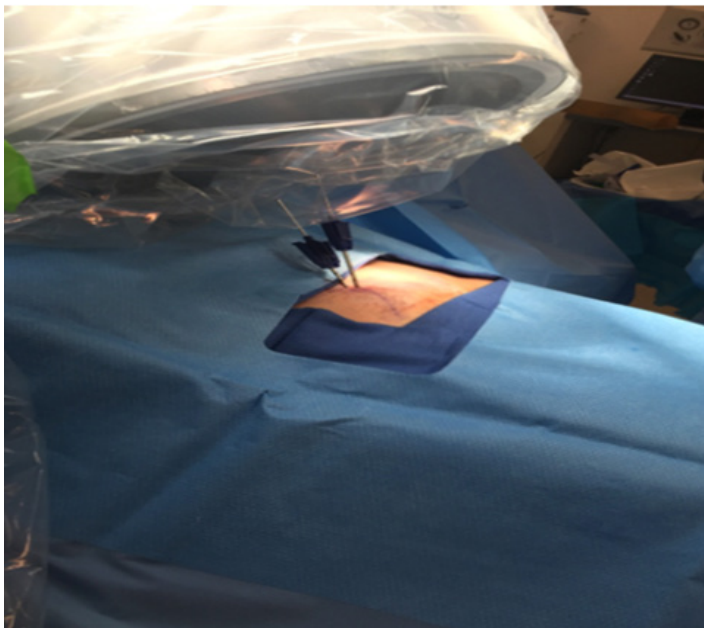


Figure 3: C-arm angled position and trocar placement.

Post procedure treatment medications included Ibuprofen 800 mg 1 po TID, Medrol dose pack and cyclobenzaprine 10 mg 1 po TID, in addition to opioid pain medication as needed. The combination of medications helped with inflammation and muscle soreness from the injury as well as the procedure. No superficial or deep infections were reported as a post-operative complication. No patient sustained a recognized neurologic, vascular, or urologic injury because of the pubic rami fracture fixation. Extravasation into the surrounding soft tissue did not pose any surgical sequelae post-operatively. Extravasation was viewed as adequate fracture filling.



Figure 4: Placement of Calcium Phosphate into comminuted Superior Pubic Ramus.

Note: Cannula placement and extravasation laterally.

The patients were encouraged to get out of bed to a chair on the day of surgery and stand with full weight bearing using walker and therapy assistance. The patients were followed in an outpatient clinic setting at 3 weeks, 6 weeks, 3 months, 6 months and one year post injury and treatment. Standard AP pelvis films were taken at each visit and the extent of healing and incorporation of the Calcium Phosphate was recorded (Figures 5-8).



Figure 5: CT scan of fracture Superior Pubic Ramus post fixation at 3 months with Calcium Phosphate. Incorporation of Calcium Phosphate into fracture healing.

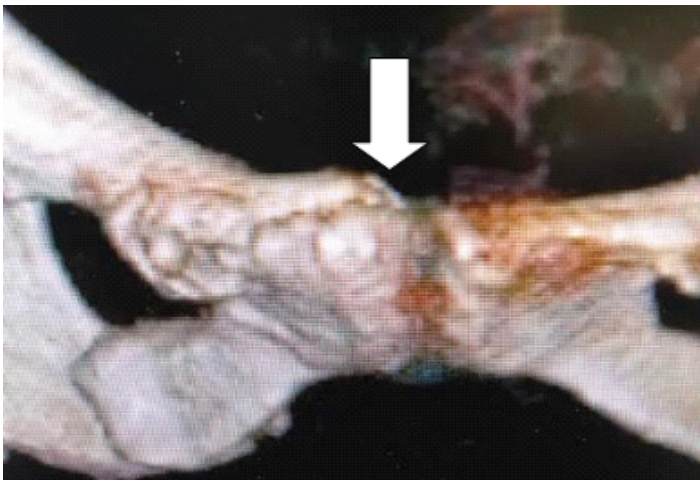


Figure 6: CT reconstruction of Superior and Inferior Pubic Rami fractures treated with Calcium Phosphate 3 months post treatment. Note the incorporation of the Calcium Phosphate into the advanced callous formation.



Figure 8. B.

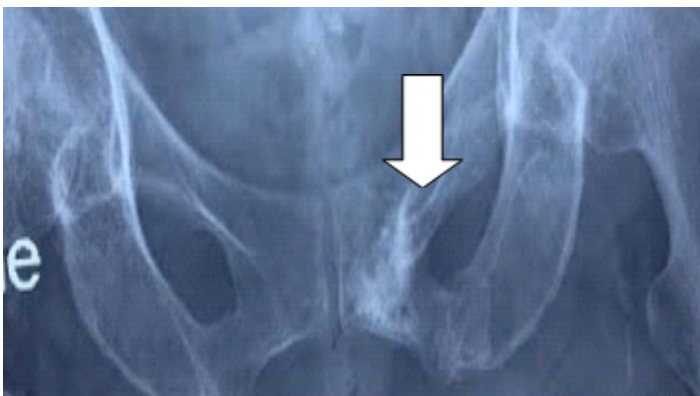


Figure 7: Incorporation of the Calcium Phosphate into normal bone healing at 9 months. Residual Calcium Phosphate is still present.



Figure 8. C.

Figures 8: A, B, C, D, E.

- Acute comminuted Superior and Inferior Pubic rami fractures.
- CT scan of Superior Pubic ramus showing severe comminution.
- CT scan of Superior Pubic ramus fracture 3 months post fixation with Calcium Phosphate maintaining placement without extravasation.
- Comminuted Superior and Inferior Pubic Rami fractures 9 months post treatment with Calcium Phosphate.
- Comminuted Superior and Inferior Pubic Rami fractures 1 year post treatment with acute comminuted hip fracture. Note no acute changes within healed Pubic Rami fractures.

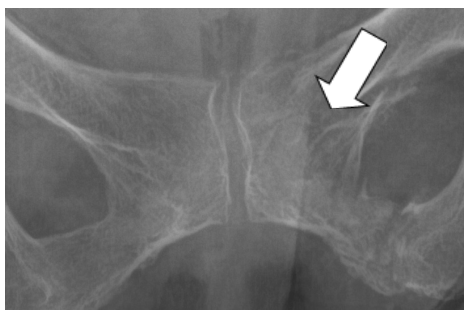


Figure 8. A.



Figure 8. D.



Figure 8: E.

Discussion

Fragility fractures of the pelvis are the result of a low-energy trauma which occurs in elderly patients who have a decrease of bone mineral density. These fractures are associated with significant loss of functional independence affecting the quality of life. These fractures involve the anterior pelvic ring which are painful and affect the patient's mobility. Fragility fracture treatment has been suggested to be linked to classification systems. The AO/OTA classification system has found to be of little use in recommending specific treatment protocols, however a more practical system has been suggested by Rommens and Hoffman known as the FFP classification. The fracture type and the patient's pre-injury mobility have been part of the treatment decision. Comminuted fragility fractures of the anterior pubic rami deserve special attention regardless of the classification system. The examples presented here were comminuted FFP Types Ia which would be difficult to treat with trans pubic screw fixation. This study suggests all patients should be treated, including FFP Types Ia to decrease pain and increase mobility avoiding bed rest and immobility.

Current surgical procedures include retrograde trans pubic screw fixation for anterior fragility fractures. Posterior ring fractures should be treated together with the anterior fractures when applicable. In the patient population reported here there were no posterior ring fractures. These surgical recommendations are not without complications. Even though there may be no vascular, neurologic, or urologic complications other problems with this form of internal fixation does occur. In one study only 39% yielded excellent fracture reduction, 10% of the screws had problems with suboptimal placement, hematoma formation and infection. Secondary fracture displacement was seen in 56% [17]. There was revision surgery in 13 % for screw displacement and loosening. Even with these results retrograde trans pubic screw osteosynthesis was touted as a reliable method for splinting of fragility fractures of the pubic rami.

In another study, patients had more significant post-surgical pain at days three and four as compared to a non-operative group. Patients

who were treated surgically were not able to stand or walk on day three as compared to the non-operative group. The complication rate was found to be 17.91 % [18].

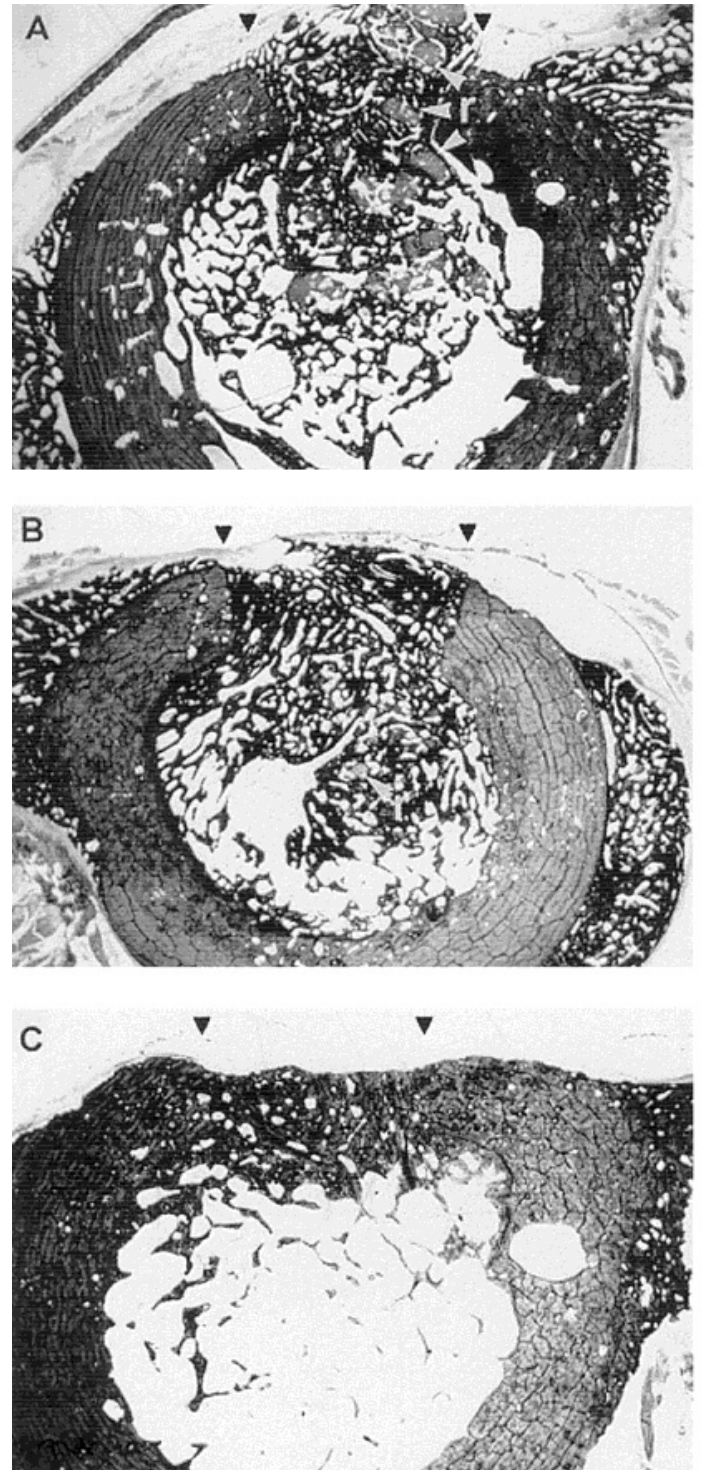


Figure 9: Femoral defect healing. In these figure, representative photomicrographs of cross sections through the femoral slot bone defect sites are presented. Sites implanted with ABS are shown at (A) 3 weeks, (B) 4 weeks, and (C) 12 weeks. (A) Non resorbed residual ABS is seen as pale gray granular to crystalline material surrounded by new spicules and

trabeculae of bone that extend into the marrow cavity (center of the bone ring) and along the periosteum (outer bone edges). (B) ABS is not seen; trabecular bone growth is still periosteal and endosteal. (C) Defect is filled with compact, lamellar bone with some spicules in the marrow. (Knaack, D, Goad, M. E. P., Aiolova, M, Rey, C, Tofighi, Ali, Chakravarthy, P, and Lee, D. Resorbable Calcium Phosphate Bone Substitute. 1 ETEX Corporation, Cambridge, Massachusetts 02139 2 Institute National Polytechnique de Toulouse, Toulouse, France Received 25 February 1998; accepted 4 August 1998, reproduced with permission).

More recently, improved Calcium Phosphate materials with chemical compositions and crystalline structures closely mimicking superior resorptive and Osseo integrative properties have been developed [19]. A synthetic Calcium Phosphate bone substitute (ABS) (a-BSMTM, ETEX Corporation, Cambridge, MA) is reported here. This ABS material also exhibits endothermically initiated hardening, which is significantly accelerated at body temperature. This endothermic setting - behavior allows extended surgical working time and injection ability at room temperature. The material is structurally like bone and exhibited almost complete resorption within 1 to 2 months following implantation (Figure 9). This material has been found to be advantageous in management of other orthopedic problems as well as bone defects [20,21].



Figure 10: Patient 3 weeks from treatment. Full protective weight bearing.

In this study all patients sustained FFP Type Ia fractures, with significant comminution. These fractures were reportedly treated non-operatively in previous studies. Our patients reported significant pain and limited mobility on admission. The surgical procedure using the Osteobiologics Calcium Phosphate was found to lend itself to management of these fragility fractures even those with substantial comminution. There were no operative or peri-operative complications. Patients were encouraged to be out of bed on the day of surgery and could be full weight bearing. Post-surgery follow-up, in the outpatient setting, demonstrated fracture healing and incorporation of the Calcium Phosphate into the fracture callous. There was seen residual Calcium Phosphate in the healed fracture site at one year from treatment comparable to that reported in the literature. Extravasation of the Calcium Phosphate from the fracture site did not have any impact on the surrounding soft tissues. This procedure was found to be safe, with minimal risk of infection, bleeding, or failure of fixation, as reported in other studies and had a significant benefit for stability, patient satisfaction and early mobilization (Figure 10).

Conclusion

The aim of the present study was to describe an Osteobiologics treatment for FFP Type Ia fractures of the pubic rami and their radiographic post-surgical findings. Type Ia fractures have been reported to be treated conservatively without surgical intervention. These patients suffer from the severe pain and immobility from Type Ia pelvic fragility fractures as the other types. The use of Calcium Phosphate optimized patient pain control and mobility. The procedure is minimally invasive, without major perioperative complications and has high patient satisfaction as previously reported. The research utilizing Calcium Phosphate as a fracture stabilizer has demonstrated the incorporation of the Osteobiologics in the fracture callous. The radiographic results in this study demonstrated the incorporation of the Calcium Phosphate into cancellous bone healing with minimal material left at 1-year post treatment. Extravasation into the soft tissue surrounding the fracture site did not cause any surgical complications.

Fragility Fracture treatment with Calcium Phosphate is minimally invasive, with no complications including bleeding, urologic and infection being reported. The technique is easily performed, and the Calcium Phosphate flows to fill the fracture. Radiographic follow-up shows fracture healing progressing with no evidence of non-union or displacement of the biologic material. The advantage of this procedure makes it applicable to treat all FFP fractures regardless of type where applicable. This study suggests Calcium Phosphate use in treating comminuted Type Ia fractures where trans pubic screw fixation would be less than optimal. These patients will benefit from this treatment option experiencing low risk, minimally invasive and maximal benefit improving pain control and early mobilization.

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