

A Computed Tomography Scan Assessment of Synthetic Multiphase Polymer Scaffolds Used for Osteochondral Defect Repair

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Purpose: To evaluate the radiographic response of a synthetic multiphase implant at various intervals after implantation and assess the nature of bone ingrowth into the implant location. **Methods:** Patients undergoing autologous osteochondral transplantation for full-thickness condylar defects with the donor sites filled by use of a synthetic implant were evaluated by computed tomography (CT) scan for the density at both donor and recipient sites. Hounsfield unit (HU) readings were obtained at the synthetic implant, transplanted autograft plug, soft-tissue, cancellous bone, and cortical bone sites. The implant site material was graded by an established ossification quality score (range, 1 to 4). **Results:** Nine patients underwent CT scans at intervals ranging from 2 to 63 months after surgery. This sequence of images tracked the potential development of bone ingrowth activity. Postoperative imaging confirmed complete autograft bone plug healing. The synthetic implant site CT scans showed a drop in density from 84 HU at 4 months to 19 HU by 13 months (fibrous scar density). The ossification quality score for all synthetic implants was 1 (tract filled with soft-tissue density) instead of 4 (cancellous bone). The transplanted autograft plug densities were consistent with and completely incorporated into the adjacent cancellous bone. **Conclusions:** The synthetic multiphase implant showed no evidence of bone ingrowth, osteoconductivity, or ossification. The implant density declined over time to that of fibrous scar. This synthetic plug does not provide subchondral structural support for any tissue that grows over it. This study does not support the use of this implant for the primary repair of articular cartilage lesions. **Level of Evidence:** Level IV, therapeutic case series.

Full-thickness articular cartilage defects present a challenge when found unexpectedly during an arthroscopic procedure. Arthroscopic options for treatment include debridement,¹ marrow stimulation techniques,^{2,3} and chondral-osseous autograft transfer.^{4,5} Chondral-osseous autograft transfer is

limited by autograft availability and the potential for donor-site morbidity. Repeat arthroscopic evaluations of patients undergoing arthroscopic chondral-osseous transfer showed that the donor defects fill spontaneously without bone grafting and are covered with a fibrocartilaginous scar.^{4,5}

A synthetic multiphase implant composed of polylactide-co-glycolide copolymer, 10% calcium sulfate, polyglycolide fibers, and surfactant was approved by the Food and Drug Administration in 2003 for the filling of bone voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. Since then, this synthetic implant (TruFit; Smith & Nephew Endoscopy, Andover, MA) has been used clinically to backfill the donor sites associated with autologous osteochondral transplantation procedures. Its ease of use and availability offer advantages for this application, and the porous nature

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is obvious by the visible inflow of blood into the device within minutes of arthroscopic insertion into a donor site. Some investigators have taken this device a step further to advocate its use for primary repair of full-thickness articular cartilage lesions.⁶ They consider this device to “provide a stable scaffold that encourages the regeneration of a full thickness of articular cartilage to repair chondral defects.”⁶ For such a process to occur, not only would the full thickness of the articular cartilage have to develop at the joint surface but subchondral bone support would need to be re-established. The *in vivo* replacement of this synthetic multiphase implant by bone would show its osteoconductivity and be a notable development having clinical applications. The purpose of this study was to evaluate the radiographic response of the synthetic multiphase implant at various intervals after implantation and assess the nature of bone ingrowth into the implant location. The hypothesis of this study was that this synthetic multiphase implant clinically shows osteoconductive behavior and is replaced by material consistent with subchondral bone.

METHODS

A consecutive series of 20 patients who had undergone autologous osteochondral transplantation for isolated full-thickness defects on either the medial or lateral femoral condyle since 2004 were identified. Those in whom a synthetic multiphase implant (TruFit) was used to backfill the donor sites were contacted and invited to be part of this institutional review board-approved study.

Inclusion criteria were patients aged 18 to 60 years (mean, 40 years; range, 26 to 58 years) who had a prior osteochondral autograft transplant procedure (COR System; DePuy Mitek, Raynham, MA) with donor-site backfilling with the TruFit plugs and were willing to undergo physical, radiographic, and computed tomography (CT) scan examinations of the previously operated knee. We purposely sought to examine patients at staged intervals starting as early as 2 months after surgery to obtain a baseline.

Exclusion criteria were patients with subsequent surgery and those with infections of the affected knee.

All patients were evaluated by a complete physical examination, standard knee radiograph series, and a knee CT scan. Radiographs were reviewed for evidence of healing, graft loosening, or arthritic change. CT scans evaluated the material density at both donor and recipient sites. A CT scan was used instead of magnetic resonance imaging because the former more

clearly determines the presence of any residual synthetic implant material and allows for an objective, quantitative assessment (measured in Hounsfield units [HU]) of the material at the prior synthetic implant location. Because of institutional review board concerns about excessive exposure from multiple CT scans in a single patient, only a single CT scan could be obtained for each patient. To document what happens to the synthetic implant over time, CT scans obtained at various intervals were believed to better define the material degradation response over time than a group of CT scans all obtained at 24 months or more after implantation. Because the synthetic implant is designed to degrade within less than 12 months, CT scans at 24 months would be expected to show no remaining device.

Axial and sagittal cuts for obtaining the HU focused on the synthetic implant and the transplanted autograft plug sites. Soft-tissue, cancellous bone, and cortical bone site readings were also taken for comparison. An established ossification quality score (range, 1 to 4)⁷ graded the status of the material at the synthetic implant sites. This ossification quality score ranges from 1 (tract filled with soft-tissue density) to 4 (consistent with cancellous bone). The CT scans were read by an independent board-certified radiologist who was not part of the surgical team.

The first endpoint of this study was to determine whether the TruFit synthetic implants completely degraded. The second endpoint was to determine whether there was bone ingrowth (evidence of osteoconductivity) into the femoral donor sites once occupied by the TruFit synthetic implants.

RESULTS

In this study 9 patients (8 men and 1 woman) who had undergone osteochondral autograft transplantation with the donor sites filled by use of the TruFit device agreed to return for physical, radiographic, and CT scan evaluation at intervals ranging from 2 to 63 months after surgery. This sequence of studies documented the synthetic implant degradation over time (first endpoint) (Figs 1 and 2) and the potential development of bone ingrowth activity (second endpoint). The HU density scores for the TruFit synthetic implant (donor site), the autograft insertion (recipient) site, and the adjacent cancellous bone at the different intervals are listed in Table 1. The mean femoral cancellous bone reading taken near the recipient sites was 274 HU. The ossification quality score for all synthetic implant sites is reported in Table 1.

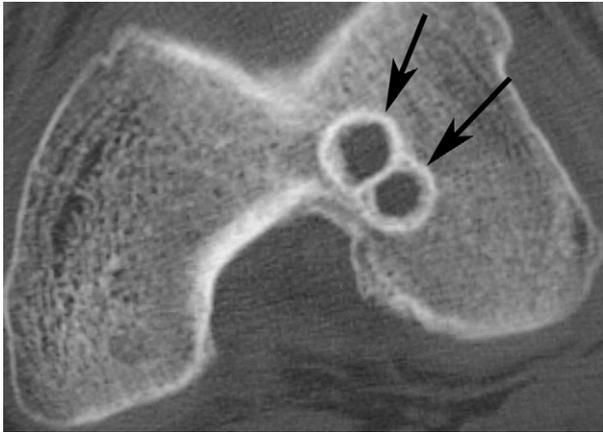


FIGURE 1. CT scan failed to show any bone ingrowth into the area of multiphase synthetic implant (arrows). © 2010 F. Alan Barber, used by permission.

Postoperative radiographs showed good transplanted autograft bone plug incorporation with no arthritic change or visible loose bodies. CT scans also confirmed complete autograft plug healing to the adjacent tunnel wall. It is noteworthy that the single long-term (63-month) evaluation showed an increased area of density that approximated that of the initial synthetic implant. Yet this density was less than the density recorded by the normal adjacent cancellous bone (322 HU). A review of this particular patient's CT scan shows a localized density at the midpoint of the synthetic implant site with voids both above and below it (Fig 3). This is not a consistent density, is remote from the surface, and would not provide support for any material at the weight-bearing surface.

At the time of the chondral-osseous transplantation, 2 of these 9 patients were treated for osteochondritis dissecans and along with 2 other patients had associated loose body removals. In addition, 5 of these patients were also treated for chondromalacia patella. Two patients in this group had no other associated procedures.

DISCUSSION

The purpose of this study was to evaluate the radiographic and CT scan responses of the TruFit synthetic implant over time and to look for the presence of bone ingrowth. No bone ingrowth was found. This sequential CT scan evaluation showed a significant change in the multiphase synthetic implant site density from 79 to 84 HU at 2 to 4 months, dropping to 19 HU by 13 months. This density (19 HU) is consistent with

fibrous scar (Table 1). The synthetic implant site density remained at the fibrous scar level through the 24- and 25-month evaluations (Figs 1 and 2). In contrast, the transplanted autograft plug showed a mean density of 304 HU (range, 191 to 437 HU), which is statistically equivalent to the mean adjacent cancellous bone density of 274 HU (range, 131 to 430 HU).

Osteochondral autografting is an accepted technique for the treatment of localized full-thickness articular cartilage defects in the weight-bearing areas of the knee. These autografts are harvested from areas with lower loads including the femoral intercondylar notch, medial femoral condyle, and lateral femoral condyle above the linea terminalis. The resulting donor-site defects are filled with a disorganized fibrocartilage. Subsequent to the removal of the graft, increased contact stresses develop at the osteochondral defect rim.⁸ Pressure-sensitive film studies in human cadaveric knees have shown that these defects are subject to substantial contact pressures.⁹ Although it has not been shown that these increased stresses result in degenerative changes in the knee, optimizing the gliding surface may help minimize donor-site morbidity and the potential for progressive degeneration. Another potential complication associated with graft harvest is bleeding in the early postoperative period from the donor sites. The use of synthetic multiphase

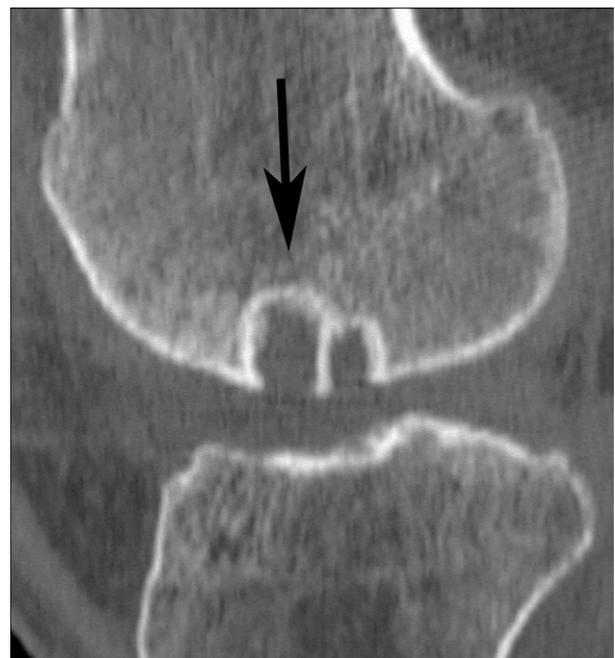


FIGURE 2. CT scan failed to show bone ingrowth (arrow). © 2010 F. Alan Barber, used by permission.

TABLE 1. HU Density Scores for TruFit Multiphase Synthetic Implant Insertion (Donor Site) and Autograft Insertion (Recipient) Site at Different Intervals

Patient No.	Interval From Implant Insertion to Postoperative CT Scan (mo)	Density (HU)			Ossification Quality Score
		Donor Site (TruFit Plug)	Cancellous Bone Near Implant Site	Recipient Site (Autograft Site)	
1	2	79	386	401	1
2	4	84	166	273	1
3	6	55	277	326	1
4	13	19	187	246	1
5	16	25	367	273	1
6	24	29	430	458	1
7	24	13	131	191	1
8	25	24	197	423	1
9	63	61	322	437	1

implants to backfill these donor sites has been shown to minimize this bleeding in animal models.¹⁰

The cylindrical synthetic multiphase implants (TruFit) are composed of polylactide-co-glycolide (75:25) copolymer, 10% calcium sulfate, polyglycolide fibers, and surfactant. The implant is created as a porous, resorbable scaffold to allow ingrowth of new tissue. It is suggested that the calcium sulfate, which dissolves in the first 3 months, enhances bone ingrowth. The polymer, which resorbs over a 9-month period, is believed to allow a gradual replacement of the scaffold by the adjacent bone.¹¹ This time frame for syn-

thetic implant degradation and disappearance is supported by the CT scan data of this study. However, there is no evidence to support osteoconductive bone ingrowth or remodeling. Any superficial soft-tissue formation is most likely fibrous scar and does not have bone beneath it to support load bearing.

The anecdotal use of these synthetic multiphase implants to fill primary femoral defects in loaded areas has been reported.⁶ This use as a primary replacement rather than as for backfilling has been associated with failure of incorporation and clinically significant inflammatory reactions with the development of foreign-body giant cells.¹²

Our hypothesis that the TruFit synthetic multiphase implant shows osteoconductive behavior and is replaced by material consistent with subchondral bone was not supported by the data from this study. Instead, our data indicate that these synthetic implants are not osteoconductive. Bone does not grow in as the porous polymer dissolves. There can be no expectation that significant subchondral support will develop for any surface layer of tissue that might develop. Although magnetic resonance images may suggest a progressive healing response, the CT scan is better suited for determining the density of the material that replaces the synthetic implant over time. Whereas marrow stimulation may create bleeding bone with the subsequent formation of a layer of fibrocartilage tissue over the defect and may provide symptomatic relief, these benefits will deteriorate over time.¹³⁻¹⁵ The use of this synthetic implant, which resorbs over a 9-month period, leaves a cylindrical cavity of fibrous tissue and creates nothing more than a large “marrow-stimulating” defect. The data from this study do not support



FIGURE 3. CT scan at 63 months in a patient showed localized density at midpoint of implant site with voids both above and below it. © 2010 F. Alan Barber, used by permission.

this synthetic implant's use for the primary repair of articular cartilage.

Weaknesses of this study include the lack of biopsy data to confirm the evidence provided by the CT scans. The number of patients included in this series is low, and because of safety issues, multiple CT scans in each patient over time were not performed.

CONCLUSIONS

The synthetic multiphase implant showed no evidence of bone ingrowth, osteoconductivity, or ossification. The synthetic implant density declined over time to that of fibrous scar. This synthetic plug does not provide subchondral structural support for any tissue that grows over it. This study does not support the use of this synthetic implant for the primary repair of articular cartilage lesions.

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