

Invisible Stabilization of Impending and Pathological Fractures A Preliminary Report on Carbon Fiber Technology

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Introduction

Stabilization of impending or pathological fractures improves quality of life in the patient with metastatic disease. While this is typically accomplished with metallic implants, this can lead to difficulty in visualization and monitoring of the fracture site with radiographic modalities. Carbon Fiber technology offers the strength, durability, and ease of placement as compared with stainless steel or titanium implants, but with the added benefit of being “invisible” on conventional radiographs and providing minimal artifact on MRI. This allows the clinician to monitor the area of concern for healing and recurrence far better than that possible with conventional metal implants.

This report provides the preliminary results of the use of Carbon Fiber plates and nails (CarboFix™) in the treatment of impending or pathological fractures due to neoplasia. Patient selection, surgical techniques and outcomes, as well as short term follow-up is presented to provide the clinician with additional and possibly improved avenues of treatment and monitoring.

Material & Methods

Fourteen non-randomized patients (ages 20 - 88) underwent stabilization of impending (8) or pathological (6) fractures of long bones treated by intra-medullary nailing (7) or plate (7) fixation using carbon fiber implants (Carbo-Fix™). (Table 1). Diagnoses included both benign and malignant bone tumors as well as metastatic disease. The surgical techniques, including methodology of interlocking screws through an invisible implant are discussed. Mechanical stability, durability, patient and implant outcomes, as well as monitoring modalities are discussed. Additionally, the implant design and clinical implications of an invisible nail is reported.

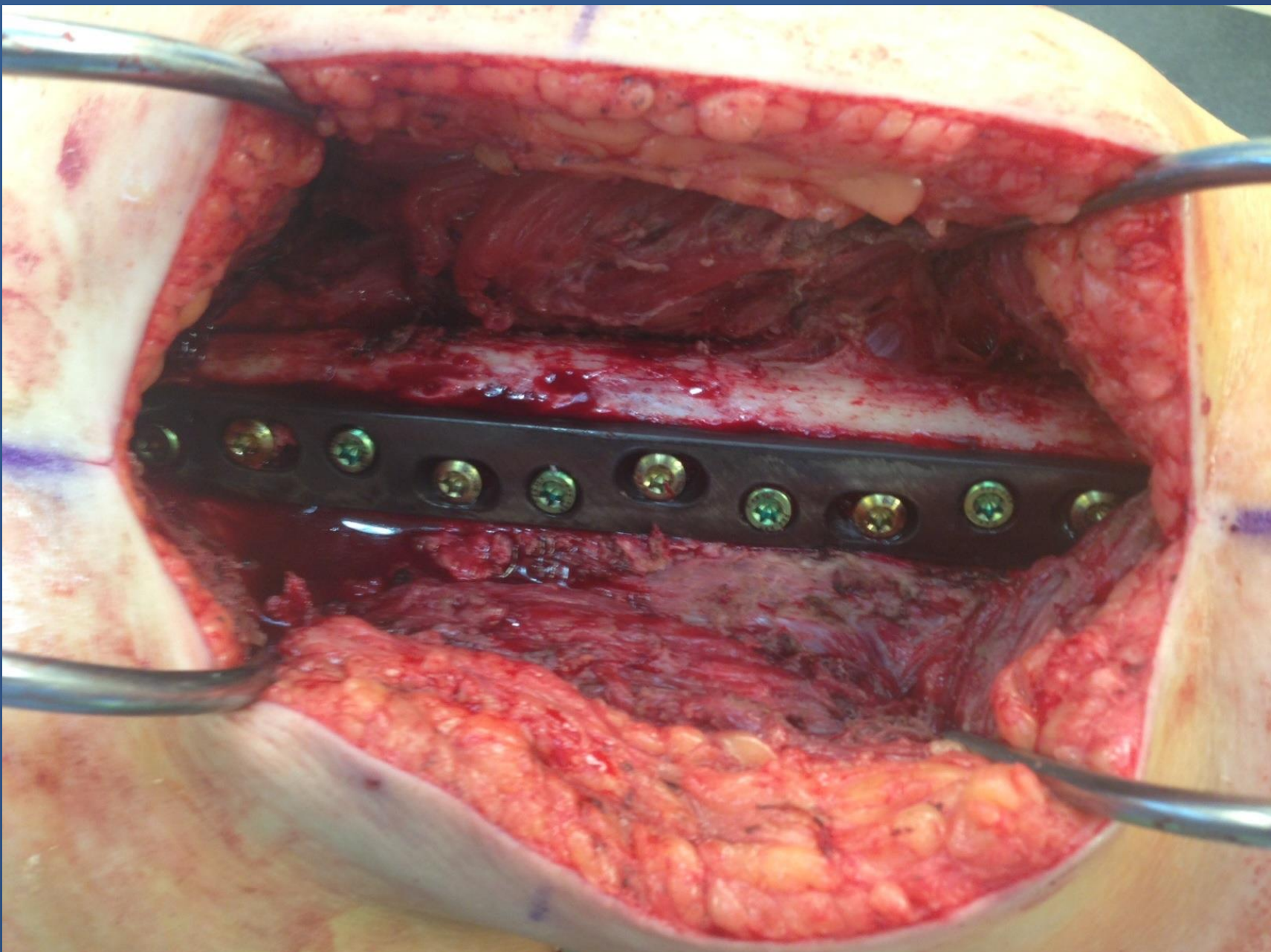
Table 1

PT	A G E	LOCATION	PLATE/ NAIL	FX/IMP FX	F/U (mos)	Union/Stability	DIAGNOSIS
1	71	TIBIA	NAIL	FX	6	UNION	RENAL
2	88	DIS RADIUS	PLATE	FX	10	UNION	SYNOVITIS
3	32	DIS RADIUS	PLATE	FX	10	UNION	GCT
4	22	DIS RADIUS	PLATE	IMP FX	9	STABILITY	GCT
5	45	PROX HUMERUS	PLATE	IMP FX	9	STABILITY	MM
6	47	PROX HUMERUS	PLATE	IMP FX	8	STABILITY	LG CHONDROSARC
7	31	HUMERUS	NAIL	IMP FX	6	STABILITY	UBC
8	72	HUMERUS	NAIL	FX	34	UNION	DESMOID
9	28	TIBIA	NAIL	IMP FX	4	STABILITY	ABC
10	29	HUMERUS	NAIL	IMP FX	3	STABILITY	UBC
11	61	PROX HUMERUS	PLATE	IMP FX	3	STABILITY	OGS
12	20	FEMUR	NAIL	IMP FX	3	STABILITY	OSTEOCHONDROMA
13	72	TIBIA	PLATE	FX	12	UNION	MM
14	81	HUMERUS	NAIL	FX	12	UNION	MET CHOLANGIO

Results

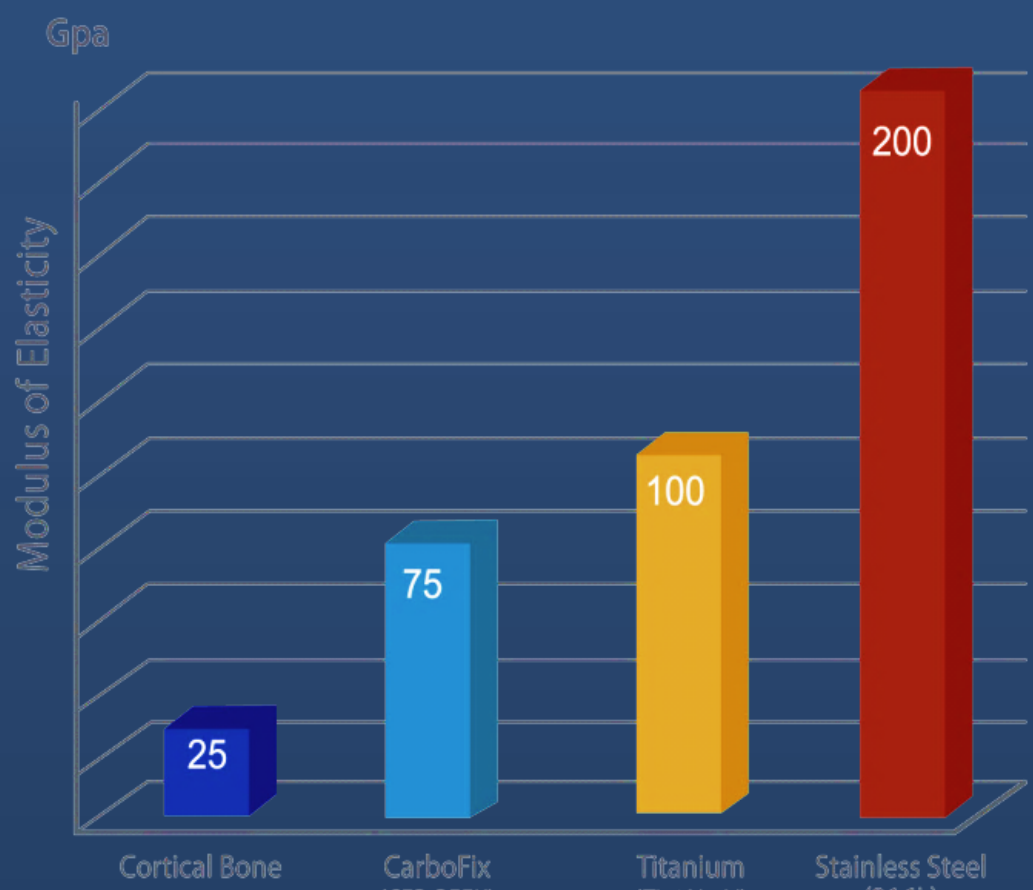
Successful stabilization was achieved in all patients. All patients were fully weight bearing or using their extremity for desired purposes in the usual amount of time for a metallic implant. (Typically by 12 weeks). Post-operative restrictions and activity levels were identical as well. Surgical time ranged from 42 minutes to 118 minutes with fluoroscopy time averaging slightly less than two minutes. There were no intra-operative or peri-operative complications. EBL ranged from 25 –150 cc and hospital length of stay ranged from 1 – 3 days. All pathological fractures demonstrated early signs of healing by six weeks and union by 12 weeks. No impending fracture progressed to fracture. Postoperative radiographs enabled the visualization of the fracture site or tumor site far more clearly due to the invisibility of the implant. Better visualization of healing was also noted. There were no obstructed views based on implant position as would commonly be seen with metallic implants.

Results



Modulus of Elasticity

The implants have a modulus of elasticity which is close to that of cortical bone, theoretically lowering the risk for stress risers and secondary fractures.



Radiographic Features

Conventional metal plate fixation vs. carbon fiber plates



Figure 3



Discussion

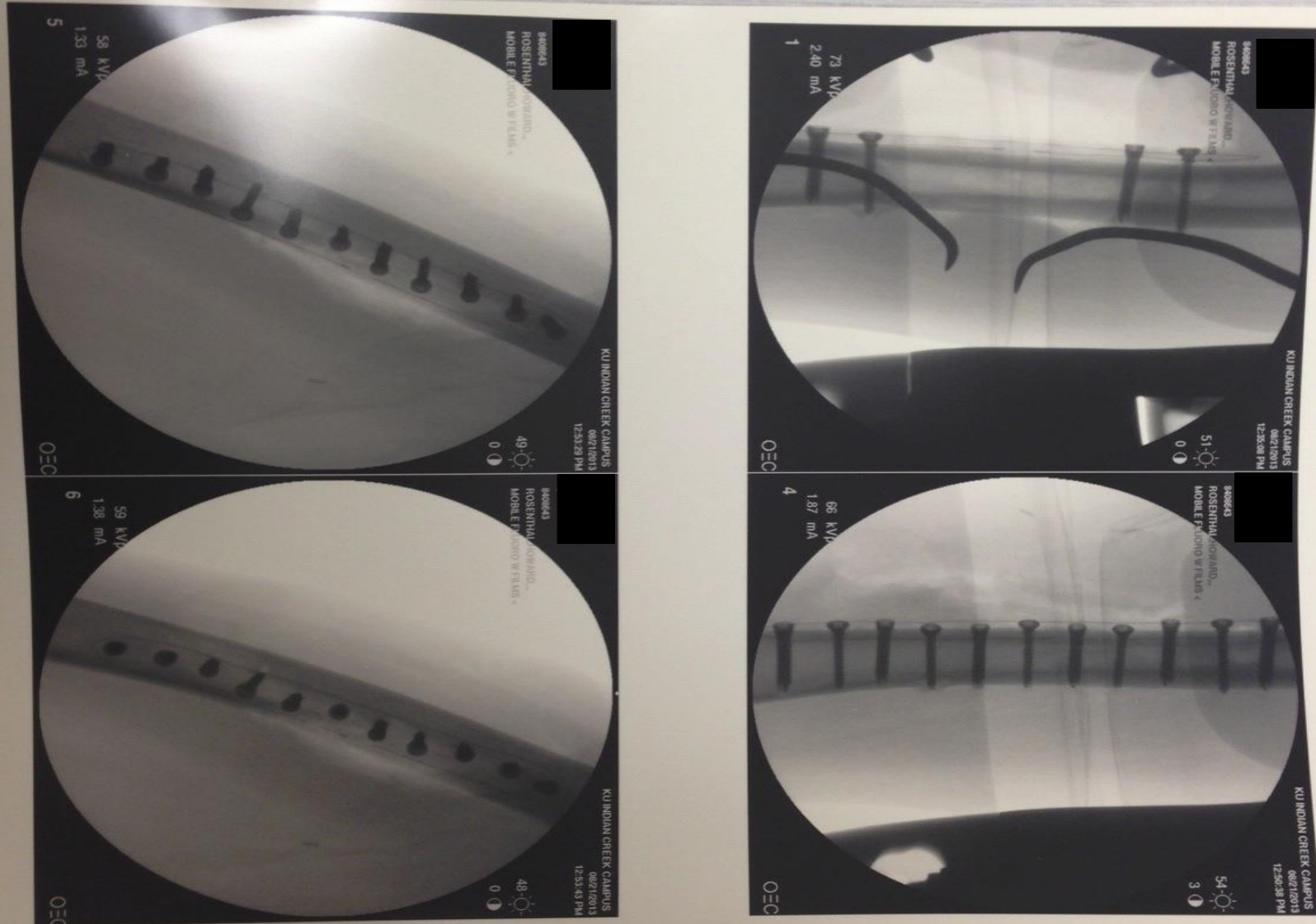
- The stabilization of impending and pathological fractures in patients with metastatic disease to the bones has dramatically improved quality of life issues. The ability to adequately fixate these fractures with implants that will outlast the expected survival of the patient likewise enables the surgeon to achieve improved performance scores and lower need for narcotics and immobility, thus frequently lengthening survival times as well. The carbon fiber implants, both plates and nails achieve this fixation and durability. In addition however, the “invisibility” of the implants allow the clinician to more adequately monitor radiographic signs of bony union, signs of local recurrence, or other complications and natural history of pathological fracture situations. The implant is MRI compatible and will not set off metal detectors.
- The carbon fibers in the implants are arranged in a unidirectional longitudinal orientation as well as a diagonal orientation, allowing for strength in all planes. The implants, due to the carbon fiber skeleton orientations, do have the drawback of not allowing for bending or molding of the plates. Therefore, the plates must be designed for specific bony locations. Locking and non-locking screw holes are available.
- The interlocking screws of the nails are placed under fluoroscopic guidance. The proximal screws are placed with a guidance system attached to the nail itself as with most nail systems. The distal interlocking holes are identified by small tantalum markers within the nail placed equidistant to the hole. When the hole is aligned properly, the tantalum markers will appear as dots rather than linear marks. (see figure 1)

Conclusion

The surgical and medical management of patients treated with carbon fiber fixation devices for impending or pathological fractures was very similar if not identical to the management of patients treated with metallic implants. The design of the implant enables the surgeon to accurately place the device in the appropriate position to secure fixation. The benefits however are quite significant in that the invisibility allows the clinician to more clearly monitor the most important area of concern, that being the fracture site, or impending fracture site, as well as the tumor location itself. The carbon fiber implant is MRI compatible and mechanically equivalent to similar implants of metallic design of the same sizes and shapes. The use of carbon fiber implants in the patients with metastatic and primary neoplasia of bone plays an improved role in our ability to monitor and therefore care for these patients.

The implants used are FDA approved for use in both trauma and pathological situations. Carbon Fiber plates and nails are manufactured and distributed by CarboFix™. CarboFix Orthopedics Ltd. 11 Ha'hoshlim St., Herzeliya 46724 , Israel
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Intra-operative Fluoroscopic View



Titanium Screw Fixation of Femoral 4.5 mm Carbon Fiber Plate

Figure 1

Tantalum Markers oriented to define interlocking holes

