

Bone grafting and internal fixation of intracapsular femoral neck fracture. Two years follow up in five patients with a novel fixation device.

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Citation

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Abstract

Objectives: To test the safety and effectiveness of a novel procedure and device for fixation of displaced or non-displaced intracapsular femoral neck fractures, in order to preserve the natural femoral head and prevent the need for partial or total hip replacement. **Design:** Single- arm, prospective clinical investigation. **Setting:** Patients admitted to the Orthopedic Department. **Participants:** Male and female patients between the ages of 50 and 75 with a Garden I-III type intracapsular femoral fracture. **Intervention:** Internal fixation with the WaisFix 100i device, and bone graft with bone substitute. **Measurements:** Experimental and computer simulator testing prior to clinical evaluation by mechanical and numerical modeling, and clinical and radiological follow-up. **Results:** Five women with Garden I-III type intracapsular femoral fracture underwent internal fixation and bone graft with the WaisFix 100i device. The operations were performed 8 to 26 hours following the traumatic event. There were no peri-operative complications or infections, and bleeding was negligible. The average hospitalization following surgery was 4 days, and hospital rehabilitation time was two weeks. Clinical and radiological bone union (eight to ten weeks) and optimal alignment were achieved in all cases. No cases of avascular necrosis, mechanical device failure or indication for hip replacement were observed after >2 years. **Conclusion:** At >2-years follow-up, the WaisFix100i internal fixation device and bone graft for intracapsular femoral neck fractures demonstrated safety, assessed by lack of complications; and effectiveness, assessed by rigid and stable fixation and short healing time.

INTRODUCTION

As the average lifespan increases, so do the health and financial burdens posed by hip fractures. Even if the incidence rates remain stable, estimated worldwide incidence is expected to increase from 1.7 million annually in 1990 to 6.3 million in 2050 [1]. A rising trend in osteoporosis [2] will further boost this figure; a mere 1% increase in incidence is expected to result in 8.2 million cases annually [1]. A recent study of 7753 residents in Canada revealed that one in six women over age 50 will sustain hip fracture, and that hip fracture increases the risk of death 3.2 fold [3].

Hip fracture treatment is costly, comprising 72% of the total costs of bone fractures in the year 2005, compared with only 14% of the total incidence [4]. One-year mortality rates range from 14% to 36% [5]. Deep vein thrombosis, pulmonary embolism, pneumonia, chronic pain, restricted mobility and poor rehabilitation are consequences of hip

fracture that negatively impact patients' health and quality of life.

Fifty percent of hip fractures are displaced or non-displaced intracapsular fractures [6]. Intracapsular fracture is also called "the unsolved fracture" of the femoral neck. Cannulated screws, sliding hip screws and Hansson pin-hook are commonly used for internal fixation of intracapsular femoral neck fractures. Less invasive than hemiarthroplasty or hip replacement, such techniques have demonstrated relatively few perioperative and postoperative complications [7, 8] and less operative blood loss.

However, mechanical failure, non-union, cut-out and avascular necrosis are drawbacks of internal fixation procedures. As a result, many orthopaedic surgeons prefer partial or total hip arthroplasty [5, 8-12]. In randomized trials, more repeat procedures were required following internal fixation (34– 43%) than hemiarthroplasty (4-6%)

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[13-16]. A meta-analysis of 106 published reports [17] showed that within two years of internal fixation of a displaced fracture of the femoral neck, non-union presented in 33 percent of the patients and avascular necrosis of the femoral neck in 16 percent. In a recent randomized controlled trial, functional outcome, as assessed by higher Harris Hip Scores at 4 and 12 months postoperatively, was greater for hemiarthroplasty than for internal fixation [18]. A procedure that will achieve hip functionality while maintaining the safety advantages of minimally invasive internal fixation is needed.

The main purposes of this study were to test the safety and effectiveness of a novel device for internal fixation of intracapsular fractures. We assessed safety by the presentation of perioperative complications, bleeding, the number of hospitalization days and the presence of avascular necrosis. We assessed effectiveness using radiographs, observations of functional recovery, and the Harris Hip Score [19].

PATIENTS AND METHODS

From November 2007 to February 2009 we performed a single-arm, prospective clinical investigation to evaluate the safety and effectiveness of the WaisFix 100i (www.orthomeditec.com) for intracapsular femoral fracture fixation using intraosseous-intralesional bone grafting. All patients signed informed consent. The ethics committee of our medical center approved the study. The study design is presented in Table 1.

Figure 1

Table 1: Study design

	Visit 1		Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
Procedures	Screening	Surgery	Discharge	2 weeks follow-up	4 weeks follow-up	3 months follow-up	6 months follow-up	9 months follow-up	12 months follow-up
Informed consent	x								
Demographics	x								
Inclusion/exclusion criteria	x								
Medical & surgical History	x								
Current medications	x	x	x	x	x	x	x	x	x
Use of narcotics/pain-killers	x	x	x	x	x	x	x	x	x
Physical examination	x		x	x	x	x	x	x	x
Vital signs	x	x	x						
Femoral fracture assessment	x								
Surgery procedure		x							
Gait assessment			x	x	x	x	x	x	x
X-ray imaging	x	x	x	x	x	x	x	x	x
Physician's Satisfaction Form		x							
Adverse events documentation	x	x	x	x	x	x	x	x	x
Need of additional surgical procedures assessment		x	x	x	x	x	x	x	x
Study deviation documentation		x	x	x	x	x	x	x	x
Study exit									x

Inclusion criteria for this study were males and females between the ages of 50 and 75 with a Garden I-III type intracapsular femoral fracture. Patients with active infectious disease, terminal disease, acute cardio-vascular disease, high risk for acute cardio-vascular disease, known cognitive disorder, or a known psychiatric or neurological disease were excluded. Five women participated in this study. Their characteristics are presented in Table 2.

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Figure 2

Table 2: Patient characteristics

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Gender	female	female	female	female	female
Age at operation	57	62	71	73	74
Weight (kg)	44	60	73	70	73
Height (cm)	155	165	170	169	163
BMI	18.3	22.0	25.3	24.5	27.5
Chronic illnesses	DM, without insulin	none	HTN	HTN	DM with insulin
Side of intracapsular femur neck fracture	left	right	left	left	right
Garden classification	I	III	I	III	II
Pauwells classification	Type I	Type II	Type I	Type II	Type III
Days of hospitalization prior to 2 weeks rehab.	4	2	6	4	4
Other	Vegetarian for many years				Smokes 40-60 cigarettes / day

DM: Diabetes Mellitus - HTN: Hypertension

The WaisFix 100i internal fixation device is comprised of a sturdy, solid triangular metal cage of 17 mm diameter and 60 mm length, and non-cannulated lag screws

Figure 3

Fig.1A: The WaisFix100i Device



The cage guides parallel insertion of the screws at a recommended 100 to 110 degrees to the femoral axis. The implant-device is made of 316 L (or LVM) medical grade stainless - ASTM F138, a stainless steel bar for surgical implants.

Results of risk analysis, bio-compatibility and regulatory studies performed on the WaisFix 100i internal fixation device comply with the requirements of the Israeli National Health Ministry and the ISO 10993-1 testing materials. To determine the maximum dynamic load for the WaisFix100i

implant, mechanical evaluation of the device was conducted in two ways: (a) Finite Element (FE) modeling, in conjunction with bench tests done at the Endolab Biomechanical Laboratory, Thansau, Germany; and (b) hip joint simulator tests, performed at the Materials Mechanics Laboratory, Faculty of Mechanical Engineering affiliated with our institution.

(A) FE MODELING

A three dimensional FE model, based on MARC 2005 software (MSC Software, Los Angeles, CA), consisting of hexahedral elements with isotropic material properties, was developed. For pre- and post-processing, MENTAT 2005 software was used (MSC Software, Los Angeles, CA). Bone was modeled as two layers: cortical (2mm thickness, elastic modulus of 17 GPa and Poisson's ratio of 0.3) and an inner core of cancellous bone (elastic modulus of 0.4 GPa and Poisson's ratio of 0.3). The WaisFix100i cage was embedded in a triangular-shaped bore in the spongy bone layer and the screws were placed into the cage (both with elastic modulus of 210 GPa and Poisson's ratio of 0.3). Full contact was assumed between cage and screws, as well as between cage and surrounding spongy bone. For validation and comparison of the model results, a FE model was also conducted on a non-embedded WaisFix100i implant, which actually represented the device alone, in vitro.

The experimental bench tests that were performed on the device alone included static cantilever loading of the device and 4-point bending for the screws, at 10mm/min deformation rate. Sinusoidal cyclic loading tests were also conducted at 5 Hz with a loading magnitude between zero and 1.2 kN.

(B) HIP SIMULATOR

The implant was inserted within a proximal femur fabrication of artificial bone (3B Scientific, Libertyville, Illinois). The femur-implant complex was positioned in a joint simulator and loaded under static compression at 5mm/min loading rate up to the load of 2.1 kN (typically representing three times body weight). Additionally, compressive cyclic loading was applied at a stroke rate of 10 Hz with a force range between zero and 2.1 kN.

The in-bone embedded WaisFix100i FE model revealed a maximum Von Mises stress of 694 Mpa, compared to 2451 MPa in the non-embedded WaisFix100i model. This indicates that embedding of the cage reduces the stress within the cage compared to that on the device alone under

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the same loading forces. Though the bench tests present an extreme situation, they provide means for comparison with other proximal-femur nailing devices. The WaisFix100i nail screw yield moment of 16.1 Nm is comparable to that of the Synthes PFN nail [20-]. Cyclic loading tests revealed that the implanted device withstands 5 million cycles without mechanical failure. The loading was at 1.2 kN, evoking a maximum moment of 60 Nm.

In the joint simulator, the static experiments indicated that at a 2.1 kN load there was no movement of the screws/cage assembly relative to the bone. Inspection under the microscope did not reveal signs of failure of the screws. In the cyclic experiments, the device withstood four million cycles with no mechanical failure, nor cracks.

From the mechanical tests it was concluded that, compared with other implants, the WaisFix100i femoral assembly achieves sufficient bending strength for clinical use.

RESEARCH PROTOCOL AND SURGICAL TECHNIQUE:

The pre-operative protocol included temporary cessation of anticoagulant medications; a six-hour fast, and administration of prophylactic antibiotics that were continued 24 hours post-operatively. All the surgical interventions were performed within 8 to 26 hours of the traumatic event.

Patients were placed in a supine position on the fracture table. Closed reduction of the fracture was obtained by traction and internal rotation. Achievement of an optimal anatomical reduction of the fracture is crucial for this, as well as other fixation methods. Antiseptic draping for standard hip fracture fixation was used. The surgical procedure, similar to that of other internal screw fixation devices [21], was performed according to the following protocol.

A 3.5 mm diameter guide pin is inserted at a point 3 to 5 mm distal to the innominate tuberosity of the greater trochanter .

Vertical positioning of the image intensifier C-arm enables an AP and LAT view of the femoral neck. Through a 5-6 cm skin incision a guide pin is penetrated, directed toward the medial and distal femoral head quadrant, affording a position angle of 100 to 110 degrees with the femoral shaft axis. Under fluoroscopic vision a conical-cylindrical cannulated 11 mm diameter drill is inserted on the guide pin up to 4 cm depth. The use of a triangular shape reamer tool of the same

size as the cage gives the drilled hole a triangular shape. The empty hole that is drilled in the bone is filled with 5 grams putty of bone substitute. Following bone grafting, the triangular cage is attached to the jig-cage holder and completely inserted through the drilled hole.

Figure 4

Fig. 1B: Insertion of the WaisFix 100i device through the drilled hole and pin-guide in situ.

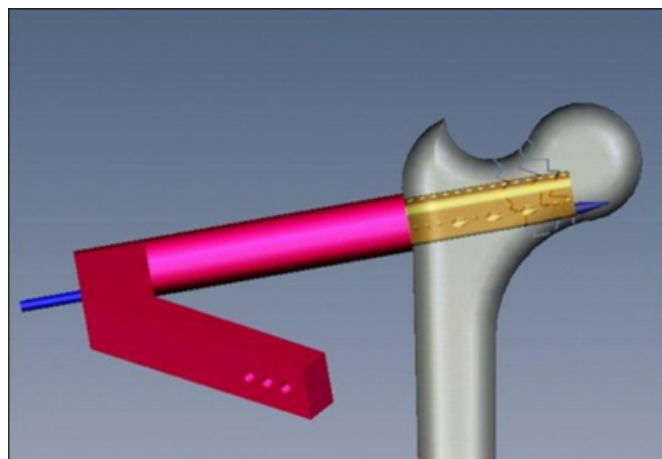


Figure 5

Fig. 1C: The area of bone grafting material surrounding the implant is marked in yellow.

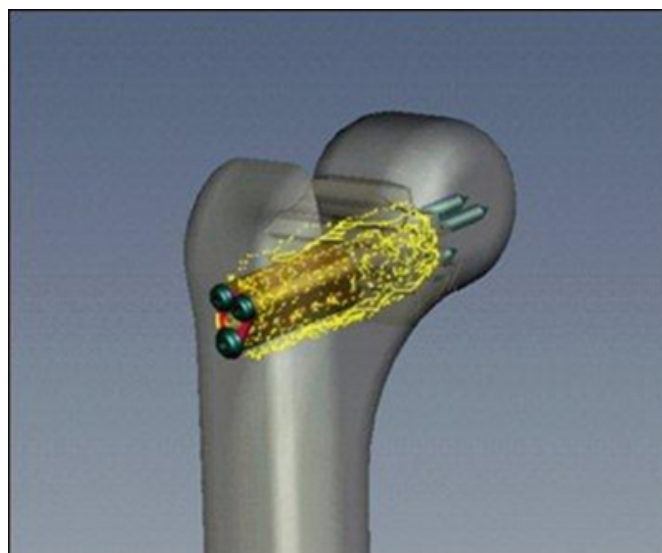
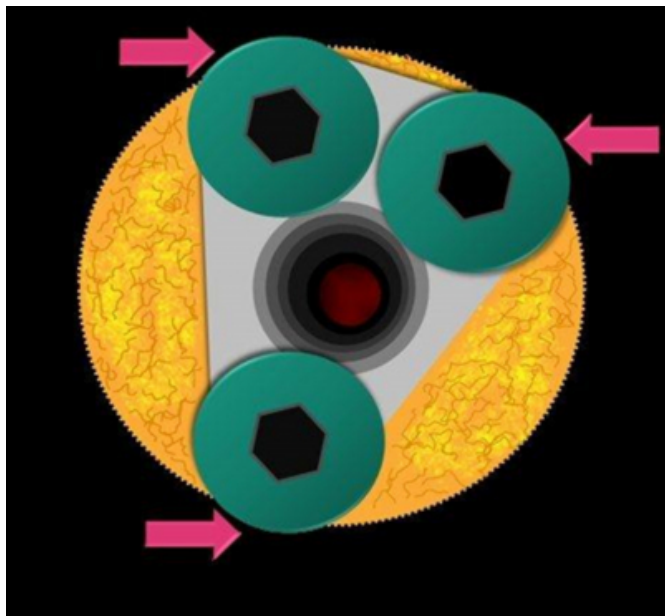


Figure 6

Fig. 1D: After bone drilling, the area of bone grafting material fills the empty space around the triangular implant. Note that the three arrows indicate metal-cortical bone contact.



Three lag screws secure the cage, anchoring it to the subchondral bone of the femoral head

Figure 7

Fig.1E: Prototype of the WaisFix 100i internal fixation device



The fascia latta is sutured by resorbable sutures, and the wound closed by 3 or 5 skin sutures and dressing. Passive mobilization of the operated limb is initiated while under general anesthesia, using fluoroscopic visualization.

Partial weight- bearing on the operated limb was allowed on the first post-operative day, depending on patient compliance, and with the aid of a walker.

Following discharge, patients were invited for post-operative visits at 2, 4 and 6 weeks; and at 2, 3, 6, 9 and 12 months. They responded to a 1 to 10 point visual pain analogue test, and to questions regarding their functional recovery. Their gait was observed and documented. At one-year post-operatively, we evaluated the five patients by means of the Harris Hip Score. Ratings for this scoring scale are excellent (90-100), good (80-90), fair (70-79) and poor (60-69).

Radiologic examination performed separately by two of the orthopaedic authors, included a frontal and a lateral hip projection. The fracture was recorded as uneventfully healed if there were visible trabeculations across the fracture line and no signs of avascular necrosis. Nonunion was defined as an absence of radiographically visible trabeculations across the fracture line, including early redisplacement or progressive deformity or displacement.

RESULTS

Results of experimental and computer simulator verification conducted prior to clinical evaluation of the WaisFix 100i internal fixation device, including rigorous mechanical and numerical modeling by means of Finite Element Analysis (FEA) found the new device mechanically sound for internal fixation of intracapsular neck fractures [20, 22].

The five cases presented in this study demonstrate the safety and effectiveness of the WaisFix 100i device for internal fixation of intracapsular hip fractures. X-rays at different stages post-operative are presented in Figures 2-6.

Figure 8

Fig.2A: Patient 1 (Garden I). X-ray at 12 months post-operative shows complete fracture healing. Note the new bone formation distal to the cage entrance.



Figure 9

Fig. 2B: Axial view, showing stable and anatomical fixation.



Figure 10

Fig. 3A: Patient 2 (Garden III). X-ray following reduction and fixation.



Figure 11

Fig.3 B: Axial view showing posterior wall comminuted fracture of the femoral neck (see arrow).

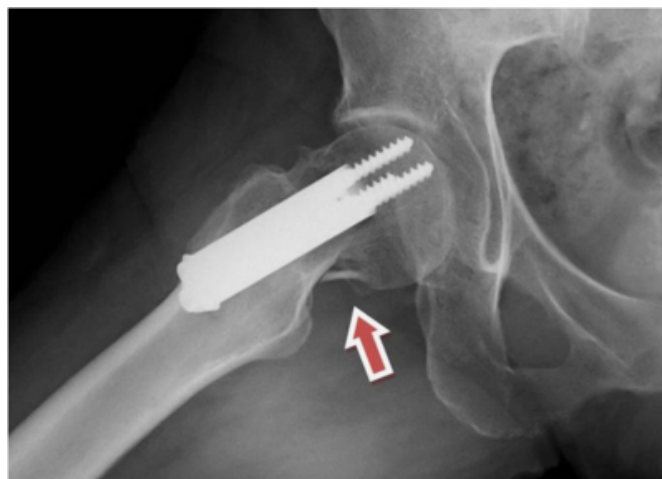


Figure 12

Fig.3C: After 4 months the fixation was removed due to trochanteric bursitis caused by the bulging cage and screws under the scar. The empty femoral neck hole was refilled by with 5 gram of osteoconductive bone substitute. Bone biopsy was taken from new bone formation at the sub-trochanteric region (see arrow).



Figure 13

Fig.3D: Bone biopsy: Immature cancellous bone fragment with osteoblast cell proliferation. (Hematoxyline-eosin - augmentation 10).

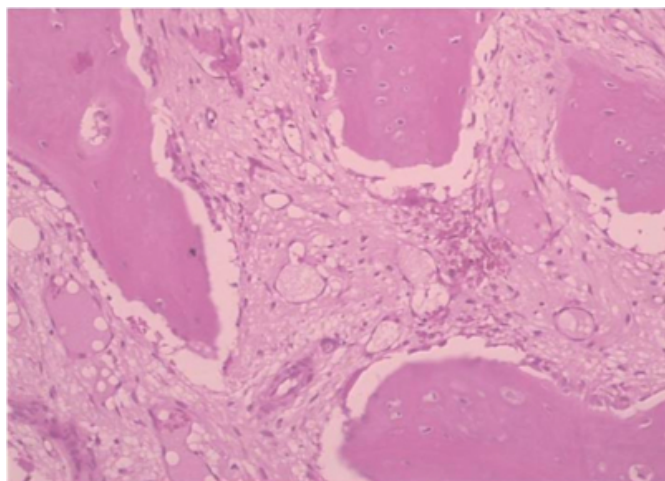


Figure 14

Fig.3E: Rich osteoblast cell lines (arrow) from the bone graft area (augmentation 40).

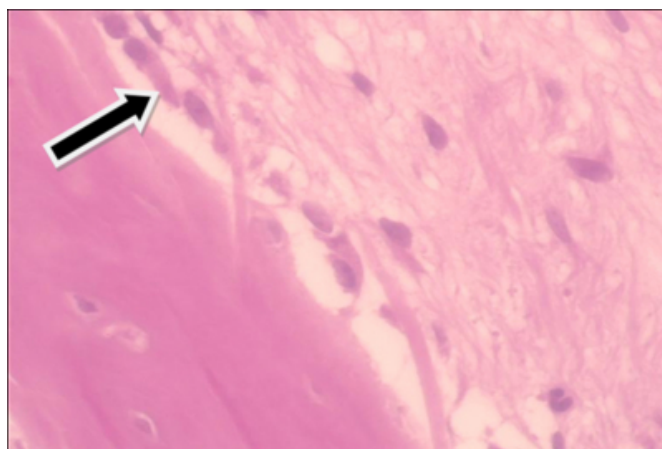


Figure 15

Fig.3F: X-ray showing complete bone healing with 1.5 cm femoral neck shortening at 12 months post-operative.



Figure 16

Fig.4: Patient 3 (Garden I). X-ray at 12 months post-operative showing complete fracture healing in the anatomical position. Note the new bone formation around the implant entrance at the trochanteric area.



Figure 17

Fig.5: Patient 4 (Garden III). X-ray at 12 months post-operative showing complete fracture healing in anatomical position. Note the new bone formation distal to the device entrance.



Figure 18

Fig.6: Patient 5 (Garden II). X-ray at 12 months post-operative showing complete fracture healing with 1.5 cm femoral neck shortening. Note the new bone formation distal to the device entrance.



Regarding safety, there were no peri-operative complications or infections. Bleeding was negligible. The average number of hospitalization days following surgery was 4; the range 2 to 6. Only one patient felt pain at 4 months (trochanteric bursitis) due to device bulging, and this was minimal at 6 months (Table 3). The radiographs, self-evaluation of pain and functional recovery attest to the absence of avascular necrosis in all five patients in a follow up of more than 2 years.

The follow-up observations and results of the Harris Hip Score and patients outcome demonstrate the effectiveness of the novel device. For all patients, partial weight bearing was achieved after 1 day, and full weight bearing at 4-6 weeks post-operatively.

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Figure 19

Table 3: Patient Outcome

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Visual Analogue Score of Pain (VAS) 3 months post-operative	1	2	1	1	0
(VAS) 4 months post-operative	0	2	0	0	0
(VAS) 6 months post-operative	0	1	0	0	0
Gait analysis 3 m. post-op: Climbing 2 flights of stairs	Not limited	Not limited	Not limited	Not limited	Limited
Walking more than 1 km	Not limited	Not limited	Not limited	Not limited	Limited
Limping	Not at all	A little	Not at all	Not at all	A little
Patient return to previous activities: 3 months post-op	Complete	Complete	Complete	Complete	Complete
Harris hip score: one year post-op	100	92	100	100	85

Of note, in patients 1 and 2 the metal cage was not inserted to the desired depth, and protruded somewhat outside of the greater trochanter. This did not cause discomfort to patient 1. Patient 2, however, felt pain in the area of the surgical scar one and a half months following the operation. At 13 weeks, post-operative trochanteric bursitis was suspected. Following clinical and radiological verification of femoral neck fracture healing at 4 months post-operatively, the cage and screws were removed in a 15-minute operation under short general anesthesia (Fig. 3). The patient was discharged the following day. The pain of the trochanteric area ceased completely, and the inflammation completely disappeared. At five days post-operatively, she returned to work. Follow-up of her gait and X-rays have been satisfactory since. The complication was considered a minor adverse event, and the internal fixation was assessed as successful due to complete fracture healing before removal of the implant device.

At one-year follow-up, revision surgery was not needed for any of the patients. None showed avascular necrosis, pseudoarthrosis or mechanical failure of the fixation. X-rays of all patients demonstrated full healing of the fractures. Rehabilitative hospitalization did not exceed two weeks for any of the patients. Four women walk without any need of support. Patient 5, who suffered prior to the surgery from chronic dizziness and from recurrent falls, was advised to walk with the aid of a walker.

DISCUSSION

Internal fixation is less invasive, requires shorter anesthesia time and entails less blood loss than partial or total hip replacement. However, due to the poor results and failure of currently available internal fixation devices, mainly in

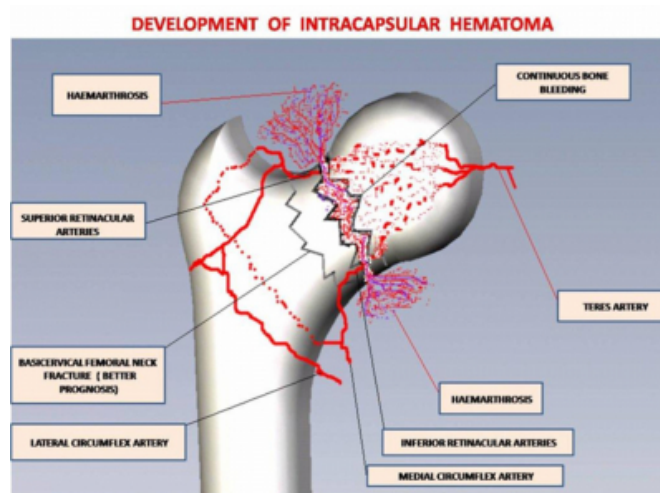
displaced fractures, partial or total hip arthroplasty is generally preferred. With that background, the purposes of this study were to test the safety and the effectiveness of a novel procedure and device for intracapsular femoral fracture fixation.

Both in vitro and in vivo testing demonstrated the safety and efficacy of the WaisFix 100i device. The combination of FEA and experimental studies is recognized as crucial to the verification of implantable orthopaedic devices [22].

The safety of the WaisFix 100i device compares with the safety of other internal fixation procedures [7, 8]. The Wais-Fix 100i device facilitates continuous post-operative drainage of hemarthrotic blood to the peritrochanteric soft tissues through multiple and central cage holes. These may contribute to decreased risk of hip tamponade due to development of intracapsular hematoma (hemarthrosis).

Figure 20

Fig.7A



Bone grafting and internal fixation of intracapsular femoral neck fracture. Two years follow up in five patients with a novel fixation device.

Figure 21

Fig. 7B

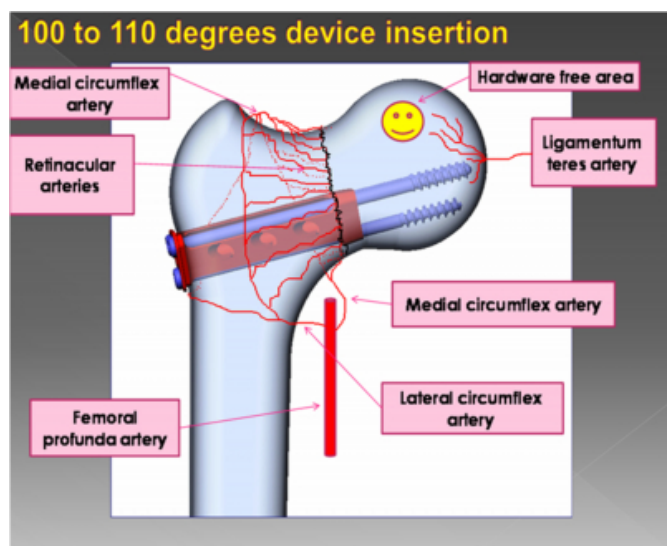
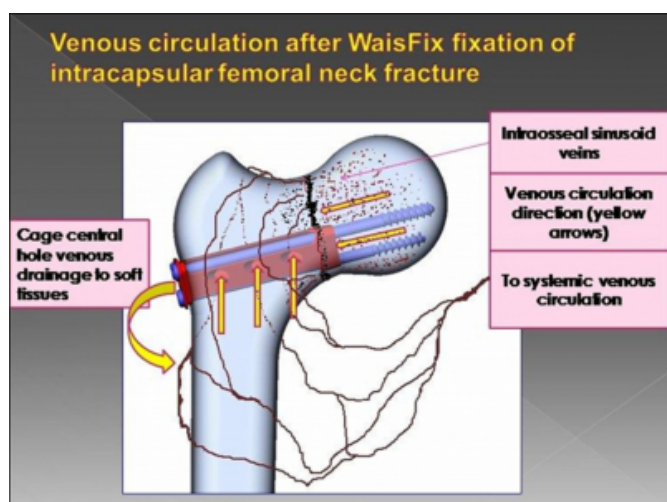


Figure 22

Fig. 7C



Consequent possible decrease of the bone intraosseous venous pressure is likely to accelerate endosteal bone healing and to minimize avascular necrosis. Though our study is too small for statistical comparisons, the lack of avascular necrosis in the five patients after 2 years only, is noteworthy.

Intracapsular fracture disrupts intraosseous cervical vessels. Peripheral callus does not form at the intraarticular part of the femoral neck. Therefore, healing is dependent on endosteal union alone, and femoral head nutrition is dependent on the remaining retinacular vessels and possibly partially from the teres ligament artery.

Arterial supply from the teres ligament continues after the intracapsular fracture, with bone bleeding contributing to the development of an intraarticular tamponade and elevated intraosseous vascular pressure of the femoral head (Fig.7A and 7C). Venous drainage from the proximal fragment of the femoral neck and head after the fracture does not occur through the teres ligament (Fig.7C). The existence of venous circulation-drainage in the adult hip teres ligament was never demonstrated or described in phlebography studies [23]. Optimal anatomical reduction and fixation may facilitate venous drainage through the intraosseous venous network of the proximal fragment of the fractured femoral head and neck, through the spongy bone of the distal fragment and through the multiple holes of the inserted cage- device. This may be a significant factor in preventing development of avascular necrosis or non union.

Regarding effectiveness, we achieved complete clinical and radiological bone union (8 to 10 weeks), optimal fracture reduction, and alignment in five women with Garden I to III type intracapsular fractures. Mechanical device failure or indication for hip replacement did not present in any of the patients. The Harris Hip Scores at one-year post-operatively are high compared to those of both hemiarthroplasty and internal fixation in a recent study [18].

The biomechanical features and structure of the WaisFix 100i device may affords important functional advantages over other internal fixation methods. The triangular cage affords optimal neutralization of inter-fragmentary rotational and shearing forces. It shortens the leverage forces of the screws by acting as a beam that anchors the trochanteric cortex and supports the calcar femori. Drilling up to the fracture line (11 mm drill diameter) prior to device insertion may decrease the bone intraosseous venous pressure into the femoral head (Garden I cases), and allow immediate evacuation of the intracapsular haemarthrosis through the fracture line between the bone fragments (Garden II and III cases). Filling of the drilled hole with bone substitute containing demineralized bone matrix (DBM), comprising a full complex of Recombinant Human Bone Morphogenetic Proteins (BMPs - Orthoblast II® Isotis Orthobiologics, Irvine, California) conveys the osteoconductive signal, enhances and accelerates bone healing of the weakened osteoporotic fractured femoral neck. Insertion of 3 lag screws in the direction of the acetabular notch, at 100 to 110 degrees, instead of the common 135 degree angle, minimizes damage to the upper pole intact intraosseous vascularization

and to the subchondral bone of the weight-bearing cartilage. The 100-110 degree inclination, which differs from all existing fixation devices, optimizes structural stability by supporting the calcar femori, and may minimize the chance of cut-out in cases of severe osteoporosis in which screws may over-penetrate the joint post-operatively.

The solid non-cannulated lag screws and cage of the WaisFix100i device anchor securely at three points: the trochanter cortical bone, the calcar femori and the subchondral bone of the femoral head, ensuring compression and securing fragment fixation. The 3 lag screws inserted through the cage channels into the bone act as short, anchored, cantilevers, enhancing flexural stiffness and minimizing deflection. Extension of 1 or 2 mm beyond the fracture line, and bone grafting into the fracture line (intralesional) and around the cage, increase cage rigidity within the fracture site. Bone build-up and anchorage compensate for the weakening effect of volume penetration of the cage.

The relatively short healing time achieved in our patients is apparently due to both the high inter-fragmentary lag screw compression of the implanted device (mechanical factor), and to the intralesional-intraosseous bone grafting (biological factor). The latter is particularly important since the main shortcoming of current internal fixation procedures is that they do not resolve the local-intralesional problem of poor bone quality (osteoporosis).

Three essential elements of bone formation are promoted by the bone graft and rigid fixation described:

- 1) osteogenesis and angiogenesis: mainly due to the exclusive property of osteogenic precursor cells found in the fresh drilled femoral neck bone marrow.
- 2) osteoinduction: proliferation and differentiation of mesenchymal stem cells into bone forming cells, stimulated by osteoinductive properties of the recombinant bone morphogenetic proteins (BMPs) present in the demineralized bone matrix (DBM) contents of the bone substitute graft used.
- 3) osteoconductive scaffold (calcium phosphate and calcium sulfate): supporting the attachment of osteogenic precursor cells.

The mechanical functioning of current internal fixation devices falls short of those of partial or total hip arthroplasty.

After more than 80 years experience and more than 100 different methods and devices, the concept of internal fixations of hip fractures remains unchanged, and still focuses on obtaining stable osseous support of the femoral head on the femoral neck. The fixation goal is stabilization, compression of the fragments and maintaining the reduction during the healing period. The current rate of complications and failure of fixation [5, 8-17, 18] is high compared with other areas of modern orthopaedic trauma practice. The goal of our novel concept is to obtain optimal mechanical fixation together with optimal biological local treatment of the frail osteoporotic fracture: bone grafting, prevention of further damage to the remaining arterial supply, and facilitation of the intraosseous venous drainage of the femoral head. The real challenge is preservation of the femoral head and prevention of major surgery: hemiarthroplasty or total hip replacement.

In our study we used bone graft substitute material that comprises a complete complex of BMPs. This material was reported to have optimal osteoinductive properties. A recent prospective case-control clinical study of 11 patients who underwent posterior lumbar fusion using recombinant human bone morphogenetic proteins demonstrated that this material can be used as the sole source of osteogenesis with success equivalent to autologous bone graft [24]. The effectiveness of mesenchymal stem cells from bone marrow sources in accelerating bone healing opens new hopes for osteogenesis. These stem cells (osteoprogenitors), combined with BMPs and DBM, may provide the ideal combination to be used with reliable internal fixation.

The authors of a recently published review of evidence-based medicine of implants for the fixation of femoral neck fractures [25] concluded that the orthopaedic community should continue to direct research and development efforts toward creation or identification of the ideal surgical implant to fix this "unsolved fracture".

Other published articles [26, 27] concluded that a general lack of consensus exists among orthopaedic trauma surgeons in the management of displaced femoral neck fractures and the orthopaedic community has yet to identify the best approach for internal fixation. The issue is unresolved and solutions will likely come from larger randomized trials comparing new devices for fixing the hip.

Both recommended the need for future research. Moreover, in a well evidence-based article [28] the authors conclude

that advances in the use of bone graft substitutes may finally improve the outcome of internal fixation of femoral neck fractures.

Our small sample clinical trial preliminary results suggest that the new device and bone grafting may provide the rigid and stable fixation lacking in other internal fixation devices, while maintaining the advantages inherent to minimally invasive procedures and applying a more biological concept using bone graft substitutes. The five cases are still under close follow-up without clinical or radiological deteriorations.

The limitations of this study are its small sample size and follow-up time. However, the first year follow-up and results, are considered acceptable for assessment with the Harris Hip Score [19], and were sufficient to meet the purposes we set for this study. Time will verify the long-term efficacy of this novel method and device, particularly whether it reduces indications for revision surgery.

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