

Manuscript Number: JOMS-D-14-00484R2

Title: Stair ascent and descent in assessing donor site morbidity following osteocutaneous free fibula transfer. A preliminary study

Article Type: Full Length Article

Section/Category: Surgical Oncology and Reconstruction

Corresponding Author: Prof. Chiarella Sforza, MD, PhD

Corresponding Author's Institution: Universita' degli Studi di Milano

First Author: alessandro baj

Order of Authors: alessandro baj; nicola lovecchio; alessandro bolzoni; andrea mapelli; aldo b gianni; Chiarella Sforza, MD, PhD

Abstract: Purpose. We wanted to investigate the gait kinematic parameters during stairs ascent and descent after a fibula free flap (FFF) removal for facial reconstruction.

Methods. Eight patients who underwent facial reconstruction with FFF ascended and descended three standard steps. Their movements were recorded by a motion analyzer; gait kinematic parameters were obtained and compared to those calculated in eight control subjects.

Results. Stride time, percentage of swing and support phases did not differ among healthy or operated limb, and control subjects (Kruskal Wallis,  $p > 0.05$ ). No significant differences were found for hip and knee movements, pelvis rotation and tilt, and body center of mass displacements. During stair descent, the patients had a significantly larger pelvis inclination than the control subjects ( $p < 0.05$ ).

Conclusion. No functional limitations during stair performance were found. The only significant difference could indicate a minor control of the pelvis, and should be used to define specific rehabilitative interventions.

Dr James R. Hupp,  
Professor of Oral-Maxillofacial Surgery  
East Carolina University School of Dental Medicine  
Editor in chief, *Journal of Oral and Maxillofacial Surgery*

Milano, 1 maggio 2014

Dear Dr. Hupp,

Please find enclosed the manuscript "Stair ascent and descent: a daily task to investigate donor site morbidity following osteocutaneous free fibula transfer" by Alessandro Baj, Nicola Lovecchio, Alessandro Bolzoni, Andrea Mapelli, Aldo Bruno Gianni, and Chiarella Sforza, which I would like to submit as original material article for the publication in the *Journal of Oral and Maxillofacial Surgery*.

In consideration of the Journal of Oral and Maxillofacial Surgery taking action in reviewing and editing our submission, the authors undersigned hereby transfer, assign, or otherwise convey all copyright ownership to the American Association of Oral and Maxillofacial Surgeons in the event that such work is published in the JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY. The undersigned authors understands that if the manuscript is accepted, the Editors reserve the right to determine whether it will be published in the print edition or solely in the Internet edition of the Journal. Articles accepted for publication are subject to editorial revision.

Thank you for your kind attention.

Sincerely,

Prof. Chiarella Sforza  
Dipartimento di Scienze Biomediche per la Salute  
via Mangiagalli 31  
I-20133 MILANO – ITALY  
Tel. +39 02 503 15407  
Fax +39 02 503 15387  
e-mail [chiarella.sforza@unimi.it](mailto:chiarella.sforza@unimi.it)

Dr James R. Hupp,  
Professor of Oral-Maxillofacial Surgery  
East Carolina University School of Dental Medicine  
Editor in chief, *Journal of Oral and Maxillofacial Surgery*

Milano, 26 luglio 2014

Dear Dr. Hupp,

Please find enclosed the revised version of our manuscript Ms. Ref. No.: JOMS-D-14-00484R1  
"Stair ascent and descent in assessing donor site morbidity following osteocutaneous free fibula transfer. A preliminary study"

The precious comments and suggestions of the reviewers were taken into consideration, and the text revised accordingly. In particular:

- 1) *Section editor: Thank you for your revised manuscript. At this time, please provide a final review of your paper in terms of qualifying the small sample size. One suggestion might be to modify your title, such as: Stair ascent and descent in assessing donor site morbidity following osteocutaneous free fibula transfer. A preliminary study.*

Thank you for your precious suggestion. The title was changed accordingly. The preliminary nature of the study was added to the Aims (Introduction section)

- 2) *Managing Editor: Please submit a revised title page that includes all authors' titles (e.g. Professor, Department Head, Resident).*

Done.

We would like to thank you and the reviewers for all the time and expertise you are devoting to our submission.

I trust that the present version of MS will be suitable for publication in the *Journal of Oral and Maxillofacial Surgery*.

Thank you for your kind attention.

With my personal best wishes for the current holiday season  
Sincerely,

**Stair ascent and descent in assessing donor site morbidity following  
osteocutaneous free fibula transfer. A preliminary study.**

**Alessandro Baj, MD, adjunct professor<sup>1,+</sup>, Nicola Lovecchio, PhD, research  
associate<sup>2,+</sup>, Alessandro Bolzoni, MD, maxillofacial surgery resident<sup>1</sup>, Andrea  
Mapelli, PhD, post doc student<sup>2,3</sup>, Aldo Bruno Gianni, MD, professor and unit head<sup>1</sup>,  
Chiarella Sforza, MD, professor and department head<sup>2</sup>.**

1. Maxillofacial and Odontostomatology Unit, IRCSS Fondazione Ca' Granda Ospedale Maggiore Policlinico, Department of biomedical surgical and Dental sciences, Università degli Studi di Milano, Italy
2. Functional Anatomy Research Center (FARC), Department of Biomedical Sciences for Health, Università degli Studi di Milano, Italy
3. Department of Ophthalmology, Otorhinolaryngology, and Head and Neck Surgery, School of Medicine, Ribeirão Preto, University of São Paulo, Brazil

**+ AB and NL equally contributed to the investigation**

A. Mapelli is currently receiving a grant (Atração de Jovens Talentos - Pesquisador Colaborador no Brasil - BJT - PROGRAMA CIÊNCIA SEM FRONTEIRAS) from the Ministério da Ciência e Tecnologia – MCT CONSELHO NACIONAL DE DESENVOLVIMENTO CIENTÍFICO E TECNOLÓGICO – CNP.

MS JOMS-D-14-00484 submitted to the *Journal of Oral and Maxillofacial Surgery* on 1 May 2014 – First revision 30 May 2014 - **Second revision 26 July 2014**

**Running title:** Stair ascent and descent after osteocutaneous free fibula transfer.

**Number of Figures:** 4

**Number of Tables:** 5

**Key words:** Fibula free flap; donor site morbidity; gait analysis; stairs; motion analysis.

**Corresponding author:**

Prof. Chiarella SFORZA  
Dipartimento di Scienze Biomediche per la Salute  
via Mangiagalli 31  
I-20133 MILANO - ITALY

TEL. +39-02-503 15407

FAX +39-02-503 15387

e-mail [chiarella.sforza@unimi.it](mailto:chiarella.sforza@unimi.it)

**Stair ascent and descent in assessing donor site morbidity following  
osteocutaneous free fibula transfer. A preliminary study.**

MS JOMS-D-14-00484 submitted to the *Journal of Oral and Maxillofacial Surgery* on 1 May 2014 – First revision 30 May 2014 - **Second revision 26 July 2014**

**Running title:** Stair ascent and descent after osteocutaneous free fibula transfer.

**Number of Figures:** 4

**Number of Tables:** 5

**Key words:** Fibula free flap; donor site morbidity; gait analysis; stairs; motion analysis.

**Abstract.**

**Purpose.** We wanted to investigate the gait kinematic parameters during stairs ascent and descent after a fibula free flap (FFF) removal for facial reconstruction.

**Methods.** Eight patients who underwent facial reconstruction with FFF ascended and descended three standard steps. Their movements were recorded by a motion analyzer; gait kinematic parameters were obtained and compared to those calculated in eight control subjects.

**Results.** Stride time, percentage of swing and support phases did not differ among healthy or operated limb, and control subjects (Kruskal Wallis,  $p>0.05$ ). No significant differences were found for hip and knee movements, pelvis rotation and tilt, and body center of mass displacements. During stair descent, the patients had a significantly larger pelvis inclination than the control subjects ( $p<0.05$ ).

**Conclusion.** No functional limitations during stair performance were found. The only significant difference could indicate a minor control of the pelvis, and should be used to define specific rehabilitative interventions.

## Introduction

Since its first description by Taylor et al.<sup>1</sup>, the fibula free flap (FFF) has been widely used to reconstruct segmental long bone and mandibular or maxillary defects<sup>2-6</sup>. The possibility to harvest the flap with only bone tissue or associated with muscular and skin components makes this flap indicated in the reconstruction of bone and soft-tissue defects of the oral cavity<sup>7</sup>. The FFF presents numerous advantages including: good bone length and quality, good length and diameter of the vascular pedicle, and ease of harvest and bone shaping with osteotomies<sup>2,3</sup>. The thickness of the fibula is adequate for positioning osteointegrated implant for dental prosthesis and the distance between the donor and recipient sites allows two teams to work at the same time<sup>2,3,8,9</sup>.

Nonetheless, removal of a FFF can provoke donor site morbidity that should be attentively considered together with the advantages of mandibular or maxillary reconstruction. Indeed, the fibula is the origin and insertion of various leg and foot muscles, and the detachment and partial withdrawal of these muscles during fibula harvest can cause leg dysfunctions.

Patients may not always perceive significant functional losses because of compensatory mechanisms or because they use the donor leg only for activities of low functional demand. It also must be noted that patients operated for malignancies are more tolerable of donor site morbidity considering their desire to have complete tumor resection and a satisfactory reconstruction.

Over the past twenty years several studies investigated the morbidity after removal of the fibula free flap. These studies focused their attention on the stability of knee and ankle<sup>10</sup>, the differences in Range of Motion (RoM) of the ankle joint, the tibio-talar angle and the joint deformity<sup>11</sup>. Other studies evaluated the kinematic parameters of gait (stride length, cadence, speed, single and double support time, ankle angle) in automated way or under cognitive and visual engagement to identify any differences<sup>4,10-14</sup>.

No significant differences were observed about the parameters listed above considering the comparison with the contra-lateral side<sup>13</sup>, the pre-intervention X-ray images<sup>11</sup>, a healthy control sample<sup>10,12</sup>, and after normalization with anthropometric values<sup>4</sup>. Additionally, no differences regarding the strength of the medio-lateral compartment<sup>10</sup>, the force of the peroneus longus and of the extensor hallucis longus<sup>15</sup>, the moment of force and power in dorsal and plantar flexion<sup>16</sup>, and the power output in flexion-extension of the knee and ankle<sup>13</sup> were found.

In particular, following the directions of the British Medical Research Council<sup>17</sup>, no decrease in performance was found by therapists in the muscles of the lower limbs<sup>13</sup>. Among the others, Agarwal et al.<sup>11</sup> examined the

walking on heels and on a slope (20°), together with hopping performance, but no studies have evaluated the morbidity of donor site in a typical action of daily life: stairs ascent and descent.

Moreover, in previous reports where the donor-site morbidity was considered low or absent in most patients, the investigators used questionnaires or clinical subjective evaluations<sup>12,18-22</sup>. Whenever possible, clinical data should be supported by quantitative instrumental evaluations allowing an objective assessment of the cost/ benefit ratio.

Thus, the aim of the current **preliminary** study was to investigate the gait kinematic parameters and the displacement of the body center of mass (CoM) during the ascent and the descent performance of 3 standard steps in a pilot group of patients who had defects of the oral cavity reconstructed by a FFF. The surgical group will be compared to a control group matched for age and anthropometric characteristics.

The determination of quantitative parameters metric during the various walking phases could allow a better evaluation of motor performance, providing some insight into the possible adaptation or osteo-arthro-muscle limits of subjects submitted to FFF harvesting. In particular, evidence-based indications could be suggested to physicians and physiotherapists to improve the rehabilitation program.

## **Materials and methods**

### *Surgical approach*

The fibula osteoseptocutaneous free flap was harvested in each patient after the execution of lower limb angiography and ultrasound, or angiography of the recipient vessels. In all patients the harvested FFF included only minimal muscle cuffs around the fibula to ensure preservation of periosteal circulation. The motor nerve branch of the flexor hallucis longus muscle was separated from flap pedicle vessels and preserved.

The fibula bone was osteotomized proximally and distally, preserving about 6 cm of bone on either extremities (epiphyses) to maintain knee and ankle joint stability and for the preservation of the common peroneal nerve.

During the closure of surgical access, the flexor allucis longus muscle was sutured to the tibialis posterior muscle and to the remaining interosseous membrane with proper tension to preserve big toe flexion function. In patients undergoing the harvest of only bone tissue or of a little skin paddle, the skin wound was primarily closed.

A semi-rigid compressive medication was maintained for two weeks in all patients. Rehabilitation with the physiotherapist started 7-15 days after surgery, following a general program without specific indications for the fibular deficit.

### *Patients*

Between 2005 and 2011, 22 patients underwent reconstruction of the mandibular or maxillary region with FFF at the Department of Maxillo Facial Surgery at the Policlinico Hospital of Milan and Galeazzi Institute of Milan.

Eight of these patients (36% of the initial group) agreed to participate in this study (Table 1). At the time of the data collection, all the participants walked independently and without walking aids. The remaining patients were excluded due to refusal to participate, moving from the area, or death. All patients, after a detailed explanation of the protocol procedures and the risks, freely signed a consent for the evaluation and treatment of data that was approved by the local ethical committee. The subject under 18 years provided a verbal consent while a signed consent was provided by parents. All tests were not invasive, did not provoke pain and were not dangerous.

The study group included four men and four women with an average age of 55 years (range 17 – 76 y) and a follow-up period between 6 and 60 months (Table 1).

In five patients an osteocutaneous FFF harvest was performed, while in three patient the harvest was collected with only the bone component. In six patients the reconstructions with FFF were performed after ablation of malignant cancer, in one patient (F3) for severe osteomyelitis of the left mandibular body, and in one patient (M2) for pseudoarthrosis in a pathological fracture after malignant cancer ablation and radiotherapy. In five patients the defects involved the mandible (F2, F3, F4, M1 and M2) and in three patients the maxilla (F1, M3, M4).

No patient reported pre-surgical difficulties in normal gait and in particular during stair ascent and descent. Before the assessment all subjects were tested following the instruction of the British Medical Research Council<sup>17</sup>, and no reductions in strength (level 5 in all muscles test) and in RoM relative to the major lower limb joints were found.

A control group of similar mean age and anthropometric characteristics (standing height, body weight) was selected following these exclusion criteria: absence of neurological disease and any orthopedic problems, non-practicing sport or important physical activities but rather hobbies and free time activities similar to

patients (Table 2). Most of the control subjects were selected from relatives and friends of the patients. None had any dizziness or major visual deficits.

All control subjects also signed the informed consent after a detailed explanation of procedures. All procedures were not invasive and not dangerous, and were in accordance with the Helsinki Declaration of 1975 as revised in 1983.

### *Procedure*

#### *Instruments*

Data collection and analysis procedure were performed in the Laboratory for the Analysis of the Movement at the Department of Biomedical Sciences for Health (Università degli Studi di Milano) using a SMART optoelectronic computerized system (BTS, Milano).

The system is composed of nine cameras, equipped with Charge Coupled Device technology and sensitive to infrared light, delimiting a working volume of 2 (width) x 3 (height) x 4 (depth) m<sup>3</sup>. Before each acquisition session, metric calibration and correction of distortions were performed using a 60-cm wand, obtaining a mean dynamic accuracy smaller than 0.4 mm.

A set of 19 retroreflective markers (diameter, 1 cm) were placed on landmarks identified for their biological and functional value (Fig. 1). During the experiment the subjects wore a bathing suite, and the markers were firmly attached to the skin by means of plastic supports and double sided adhesive tape.

#### *Analysed Task*

Each subject (patients and control subjects) was asked to ascent and descend three steps. A three-step wood staircase with a step height of 16 cm (value similar to the stairs of the public infrastructure<sup>23,24</sup> and a depth of 30 cm was used (Fig. 2).

Each subject started the action 5 m before the first step<sup>24</sup> to create a performance comparable to the real situations of daily life. All subjects performed the action at their preferred speed. Testing consisted of six trials: patients and control subjects started the ascent 3 times with the right limb and 3 times with the left one, to diversify the approach to the first step (with both the healthy and operated leg). Similarly, also the descending phase, after a step on the superior floor of the structure (area, 60 x 60 cm<sup>2</sup>; Fig. 2), was begun three times with the left limb and three times with the right one.

Before data collection, all subjects became familiar with the laboratory environment and, independently, performed some trials up and down the stairs. Thus, they gained self-confidence and identified the starting

point of the march in order to climb the first step with the requested foot (right or left), without changing the stride and the speed gait more than 10%<sup>24</sup>.

Subjects wore their habitual and comfortable footwear to recreate a real situation, and walked at their self-chosen usual speed<sup>24</sup>, performing both the ascent and the descent steps without any interruption. Each subject performed the task without aids or assistance.

### Data analysis

The 3D global reference system was defined as follows:

- X-axis, parallel to the longitudinal direction of the symmetric stair structure, directed forward;
- Y-axis, orthogonal to the ground, directed upward;
- Z-axis, orthogonal to the sagittal plane (XY), directed to the right.

All film acquisitions were separated in two distinct sequences: the ascent and the descent phases. Subsequently, the extremes of the gait cycle (right and left) were determined using the interval between two consecutive unilateral heel-strikes. Thus, the gait cycle definition allowed the normalization of the stride time as a percentage of the cycle.

Then, for each gait cycle the duration of single, double support and swing phases were calculated. In particular, to verify different support times about operated or healthy limb, for each sequence, the percentage of double support was determined both for right and left steps.

The RoM of hip flexion-extension and abduction-adduction, knee flexion-extension and pelvis rotation, inclination and tilt, were also calculated. All angles were computed using the landmarks placed on the skin, without corrections to estimate joint position<sup>25</sup>. The pelvis-ground relative orientations were computed using Euler angles (sequence: rotation around Y, flexion/extension around Z, and inclination around X) starting from the three landmarks positioned on the pelvis segment (sacrum, right and left anterior superior iliac spines). For the lower limbs, hip flexion-extension and adduction-abduction were computed as the angle between thigh segment and pelvis sagittal and lateral-lateral axes respectively; knee flexion-extension was computed as the angle between thigh and leg segments projected on the pelvis sagittal plane).

The position of the CoM was estimated using Whittset's model, which approximates the human body to a group of rigid segments<sup>26</sup>. In particular, we recently devised a method including 10 body segments, as described in detail by Mapelli et al.<sup>27</sup>. In brief, the 10 segments (head and neck, trunk, arms, forearms, thighs, and legs) are defined by a cluster of 14 markers (a subset of those recorded in the current study, Fig. 1: right and left tragion, acromion, olecranon, radius styloid process, greater trochanter, femoral lateral

epicondyle, lateral malleolus). Data about the anthropometric distribution of the mass in each body segment, and about the location of its CoM, were taken from Zatsiorsky & Seluyanov<sup>28</sup>. The calculation of the total body CoM is obtained as a weighted-average of the CoMs of the different body segments.

In particular, anterior-posterior (relative to the center of the pelvis) and lateral-lateral displacements of the CoM during the task were taken into account.

### Statistical analysis

For all the analyzed variables, descriptive statistics were calculated in selected instants of the task.

In particular, the chosen instants were the unilateral heel-strike (two consecutive, corresponding to the 0% and 100% instants of the gait cycle), the toe-off and the clearance of toe phase (instant during the mid stance in which the fingers must not touch the ground to avoid falls).

Within subject, for each side, the mean and standard deviations of the RoM of knee (flexion-extension), hip (flexion-extension and abduction/ adduction), and pelvis joints (rotation, inclination and tilt) were calculated.

Anterior-posterior and latero-lateral displacements of the CoM were also calculated.

Patients and control subjects age and anthropometric data were compared by Mann Whitney non parametric test. Kinematic data were compared between patients (healthy and operated limb) and control subjects (average right-left data) using Kruskal Wallis non parametric test. Where necessary, post hoc tests were made by Mann Whitney test after correcting for the loss of degrees of freedom. For all analyses, the significance level was set to 5%. The effects size (ES) coefficient ( $d$ ,<sup>29</sup>) was also calculated to determine if the statistically significant differences found were also clinically significant. An effect size ( $d$ ) smaller than 0.3 is considered a "small" effect (a small clinically significant difference), around 0.5 a "medium" effect, and larger than 0.8, a "large" effect.

## **Results**

Age and anthropometric data of the control subjects did not differ from those of the patients (Mann Whitney test, all  $p$  values larger than 0.05).

In the patient group, on average, no statistically significant differences were observed for the temporal gait parameters (stride time, percentage of swing and support phases) when stair performance was started with the healthy or the operated limb, for both ascending or descending tasks (Table 3). Additionally, no differences were found comparing the healthy group with the patients. In general, less time was spent during the descent phase than during the ascent one, with a somewhat larger swing phase.

Hip movements (flexion-extension and abduction-adduction) did not show significant differences between control and patient groups during the three phases (heel contact, toe off and clearance) and for the total RoM (Table 4). Within patients, actions started with healthy or pathological limb were not different.

The flexion-extension performed by the knee during the three gait phases is shown in figure 3. No differences were found between control and patient group (pathological and healthy limbs) both during ascent and descent phase (Kruskal Wallis test, all p values > 0.05). During the ascent phase, only one patient reached 90 deg of flexion (clearance instant, data not shown). The mean RoM was 78 deg in the ascent phase while it reached 83 deg during the descent task. The flexion during foot clearance was very similar during the two tasks (fig. 3).

The magnitude of pelvis movements are shown in table 5. Rotation and tilt did not show statistically significant differences between the actions started with the healthy or the pathological limbs, or compared to control subjects. In particular, during the descent phase the control group used a backward tilt (negative value in the table) in all three instants, while during the ascent task all subjects (in particular during heel contact and clearance instants) performed a counterclockwise minimal rotation.

During the descent trials, the patients had a significantly larger RoM of pelvis inclination than the control subjects (Table 5). The post hoc analysis found differences between control subject movements and the action started by the patients with their pathological limb ( $p = 0.012$ ), even if the effect size revealed a small clinically significant difference ( $d = 0.31$ ).

In the patients, the CoM displacements (anterior-posterior and medio-lateral directions) were in a similar range during actions started with the two limbs, with values very close to those observed in healthy subjects, and without significant differences (Fig. 4). The maximum difference was 18 mm during the descent phase (control group vs pathological limb). In the ascent phase, the medio-lateral CoM displacement was about twice than the anterior-posterior one, while similar values were estimated during the descent phase.

## **Discussion**

Stair negotiation (ascent and descent) is an important common daily living activity. To perform the task, it is essential to keep a full efficiency of the limbs because larger muscular effort<sup>24</sup>, angular knee flexion<sup>30</sup> and ankle RoM<sup>31</sup> are needed than during level walking.

Patients undergoing FFF harvest for reconstruction of the mandible or maxilla may present alterations in gait kinematics: the absence of a part of a lower limb long bone raises the question about the rehabilitation and the performance of a typical daily activity that could significantly affects the independence and quality of life.

Moreover, the fibula functions as the origin and insertion points of various leg and foot muscles, the detachment and injury to these muscles during fibula harvest can cause leg dysfunctions.

Recent studies showed the absence of significant alterations in level gait performance (especially after 36 months of follow-up)<sup>15</sup>, while no information is available about the gait characteristics of stair climbing.

In the present study, patients performed the ascent and descent of three standard steps using the step-over-step strategy that requires lower energy cost and allows higher efficiency<sup>31</sup>. All patients were able to perform the task without support (handrail) or assistance. In general, patient data were well comparable with data collected in a reference group of healthy subjects, and no significant differences were observed when stair ascent and descent were begun with the healthy or the operated lower limb.

The stairs stride time was greater than the level walking time<sup>32</sup>, especially during the ascending phase (1.4 sec). The percentage of support (on average, 65%) and swing times were very similar to those measured in the control group, and to literature data collected in healthy adults<sup>23</sup>. In comparison to level walking, the percentage of swing decreased because the stair height (defined according to the standard size of public environment<sup>31</sup>) was less than stride length. Also, the climbing action requires extra time to perform the major power output needed during the stair performance than during level walking. Indeed, in healthy subjects the stair ascent phase requires larger internal moments and strength in knee extension than level walking<sup>23</sup>.

During the ascent and descent phases (in particular at toe off) both patients and control group showed hip adduction. This arrangement was used to best perform the toe off phase of gait, balancing the internal moment<sup>33</sup>.

From our data we could define a specific motion strategy. In particular, the hip joint during the ascent task performed a larger RoM than during a level walking task (such as reported in literature<sup>30</sup>) even if the best contribution to bypass the step was given by the knee flexion (78° during ascent and 83° during descent). In the descent phase the patients used a smaller flexion-extension hip RoM<sup>23,24</sup> than that reported in literature<sup>30</sup>. Our explanation, excluding strength reduction and RoM limitation that were not found, is based on a fear-approach to the downhill action: the patients did not use their total knee RoM.

The rotational and tilt hip movements showed a comparable trend between healthy and pathological limb and similar to the reference values of the healthy group. From a clinical point of view this indicates a good control of the pelvis in these planes. Indeed, the value of CoM displacement in medio-lateral arrangement did not exceed the healthy population values<sup>30</sup>. The only significant difference found between the control group and the patients (action started with pathological side in descent phase) could indicate a minor control of the pelvis.

In conclusion, our patients submitted to a FFF for reconstruction of major defects in the oral cavity did not present functional limitations during stair performance. The surgical treatment revealed a general positive outcome: no gait impairments during stairs negotiation were found. Some differences in pelvis movement during the descent phase were found, and these data could be used to define specific clinical and rehabilitative interventions according to improve the follow-up efficacy.

In general, we recommend:

- increasing of motor control during load transfer especially on the pathological limb
- increasing the strength of the gluteus to better manage the inclination of pelvis above all during descent phase.

This functional analysis could define a new approach to devise specific rehabilitation protocols that are still absent or scantily practiced in our national health service.

This pilot study presents some limitations: first of all the analyzed patients represent a convenience group, and no kind of selection was made apart from the possibility of stair climbing and descending without aids. Data should therefore be considered with caution and require a larger group of subjects, even if previous investigation on this topic quantitatively assessed similar numbers of patients (from 7 to 11)<sup>4,12,33</sup>, and only Lee et al.<sup>16</sup> investigated 20 patients. All previous studies concentrated on level overground gait, and in no occasion stair climbing was analyzed. This test allows to better investigate possible deficit in the anterior leg compartment (extensor hallucis longus muscle), but the current reduced number of patients prevents to extend our findings to all the patients submitted to the same surgical procedure.

We analyzed only a 3-step staircase because of laboratory dimensions: during motion analysis, all the body landmarks must be seen by two cameras at least to ensure the 3D reconstruction of landmarks' trajectories<sup>25,27</sup>. The system cannot be used outdoor, and higher staircases cannot be fit inside the working volume of the motion capture system. This experimental setting represents therefore a limitation of our study, but it focused on a daily activity of sufficiently but not too complex/ or difficult performance. Actually, longer stairs may not represent a daily trial for these patients.

Additionally, we did not position markers on the foot because they were scarcely visible by the TV cameras during the task. Foot markers could improve the kinematic model allowing further analysis about ankle RoM<sup>31</sup>, the foot inclination during landing<sup>23</sup>, and the influence of valgus position of the foot<sup>15</sup>. Furthermore, the use of a force platform could study the dynamics of load transfer, that is the instant most frequently affected by falls. The promising results of this preliminary study are being used to design a multicenter study

focusing not only on biomechanical results but also on the various surgical approaches and rehabilitation procedures.

## REFERENCES

1. Taylor GI, Miller GD, Ham FJ: The free vascularized bone graft. A clinical extension of microvascular techniques. *Plast Reconstr Surg* 55:533-544, 1975
2. Wei FC, Chen HC, Chuang CC: Fibular osteoseptocutaneous flap: anatomic study and clinical application. *Plast. Reconstr Surg* 78:191-200, 1986
3. Wei FC, Seah CS, Tsai YC: Fibula osteoseptocutaneous flap for reconstruction of composite mandibular defects. *Plast Reconstr Surg* 93:296-306, 1994
4. Lin JY, Djohan R, Dobryansky M, Chou SW, Hou WH, Chen MH, Wei FC: Assessment of donor-site morbidity using balance and gait tests after bilateral fibula osteoseptocutaneous free flap transfer. *Annals Plast Surg* 3:246-251, 2009
5. Yazar S, Lin CH, Wei FC: One stage reconstruction of composite bone and soft tissue defects in traumatic lower extremities. *Plast Reconstr Surg* 114:1457-1466, 2004
6. Baj A, Youssef DA, Monteverdi R, Bianchi B, Combi VA, Gianni AB: Reconstruction of partial maxillary defects with the double-barrel fibula free flap. *Acta Otorhinolaryngol Ital* 30:299-302, 2010
7. Baj A, Beltramini GA, Massarelli O, Youssef DA, Gianni AB: Minimally invasive harvest of free fibula flap. *Plast Reconstr Surg* 131:474e-7e, 2013
8. Kildal M, Wei FC, Chang YM: Mandibular reconstruction with fibula osteoseptocutaneous free flap and osteointegrated dental implants. *Clin Plast Surg* 28:403-410, 2001
9. Chana JS, Chang YM, Wei FC: Segmental mandibulectomy and immediate free fibula osteoseptocutaneous flap reconstruction with endosteal implants: an ideal treatment method for mandibular ameloblastoma. *Plast Reconstr Surg* 113:80-87, 2004
10. Draganich LF, Nicholas RW, Shuster JK, Sathy MR, Chang AF, Simon MA: The effects of resection of the proximal part of the fibula on stability of the knee and on gait. *J Bone Joint Surg* 4:575-583, 1991
11. Agarwal DK, Saseendar S, Patro DK, Menon J: Outcomes and complications of fibular head resection. *Strategies Trauma Limb Reconstr* 7:27-32, 2012

12. Bodde EW, de Visser E, Duysens JE, Hartman EH: Donor-site morbidity after free vascularized autogenous fibular transfer: subjective and quantitative analyses. *Plast Reconstr Surg* 111:2237-2242, 2013
13. Maurer-Ertl W, Glehr M, Friesenbichler J, Sadoghi P, Wiedner M, Haas F, Leithner A, Windhager R, Zwick EB: No adverse affect after harvesting of free fibula osteoseptocutaneous flaps on gait function. *Microsurgery* 32:362-369, 2012
14. Sieg P, Taner C, Hakim SG, Jacobsen HC: Long-term valuation of donor site morbidity after free fibula transfer. *Br J Oral Maxillofac Surg* 48:267–270, 2010
15. Ling XF & Peng X: What is the price to pay for a free fibula flap? A systematic review of donor-site morbidity following free fibula flap surgery. *Plast Reconstr Surg* 129:657-674, 2012
16. Lee JH, Chung CY, Myoung H, Kim MJ, Yun PY: Gait analysis of donor leg after free fibular flap transfer. *Int J Oral Maxillofac Surg* 37:625-629, 2008
17. Kendall FP, Kendall McCreary EK, Provance GP, Rodgers McIntyre M, Romani WA: *Muscles Testing and Function with Posture and Pain*. Baltimore: Lippincott Williams & Wilkins; 2005
18. Vail TP, Urbaniak JR: Donor-site morbidity with use of vascularized autogenous fibular grafts. *J Bone Joint Surg Am* 78:204-211, 1996
19. Goodcare TE, Walker CJ, Jawad AS: Donor site morbidity following osteocutaneous free fibula transfer. *Br J Plast Surg* 43:410-412, 1990
20. Hidalgo DA, Rekow A: A review of 60 consecutive fibula free flap mandible reconstructions. *Plast Reconstr Surg* 96:585-596, 1995
21. Shpitzer T, Neligan P, Boyd B: Leg morbidity and function following fibula free flap harvest. *Ann Plast Surg* 38:460-464, 1997
22. Shindo M, Fong BP, Funk GF: The fibula osteocutaneous flap in head and neck reconstruction: a critical evaluation of donor site morbidity. *Arch Otolaryngol Head Neck Surg* 126:1467-1472, 2000
23. Riener R, Rabuffetti M, Frigo C: Stair ascent and descent at different inclinations. *Gait Posture* 15:32-44, 2002
24. Vallabhajosula S, Yentes JM, Stergiou N: Frontal joint dynamics when initiating stair ascent from a walk versus a stand. *J Biomech.* 45: 609–613, 2012
25. Mapelli A, Rodano R, Fiorentini A, Giustolisi A, Sidequersky FV, Sforza C: Body movements during the off-ice execution of back spins in figure skating. *J Electromyogr Kinesiol.* 23:1097-1105, 2013

26. Chandler RF, Clauser CE, McConville JT, Reynolds HM, Young JW: Investigation of inertial properties of the human body. Contract No DOT-HS-017-2-315-1A, Final Report. Washington: US Department of Transportation; 1975
27. Mapelli A, Zago M, Fusini L, Galante D, Colombo A, Sforza C: Validation of a protocol for the estimation of three-dimensional body center of mass kinematics in sport. *Gait Posture* 39:460-465, 2014
28. Zatsiorsky V, Seluyanov V: The mass and inertia characteristics of the main segments of the human body. Moscow: Central Institute of Physical Culture; 1983
29. Cohen J: A power primer. *Psychol Bull* 112:155-159, 1992.
30. Neumann DA: *Kinesiology of the Musculoskeletal System - Foundations for Physical Rehabilitation*. Elsevier – Mosby; 2002
31. Reid SM, Lynn SK, Musselman RP, Costigan PA: Knee biomechanics of alternate stair ambulation patterns. *Med Sci Sports Exerc* 39:2005-2011, 2007
32. Saibene F, Minetti AE: Biomechanical and physiological aspects of legged locomotion in humans. *Eur J Appl Physiol* 88:297-316, 2003
33. Chou SW, Liao HT, Yazar S, Lin CH, Lin YC, Wei FC. Assessment of fibula osteoseptocutaneous flap donor-site morbidity using balance and gait test. *J Orthop Res* 27:555-560, 2009

**Table 1:** Anthropometric data, follow-up time and surgical data of the analyzed patients.

Patients	Age (y)	Weight (Kg)	Height (cm)	Follow-up (months)	FFF type/ side	Reconstructed Segment
F1	49	52	162	60	OC right	Premaxilla
F2	57	52	161	12	OC right	Mandibular body
F3	49	50	165	32	O left	Mandibular body left
F4	66	70	164	24	OC right	Mandibular body left
M1	17	81	190	11	O left	Mandibular body left
M2	62	75	175	6	O right	Mandibular body right
M3	66	72	172	48	OC left	Alveolar process right
M4	76	82	174	36	OC right	Maxilla
mean	55	67	170	28		
SD	18	13	9	19		

OC = osteocutaneous flap, O = bone flap.

**Table 2.** Anthropometric data of the control group subjects.

Subjects	Age (y)	Weight (Kg)	Height (cm)
F1	53	50	163
F2	65	60	168
M1	64	70	175
M2	70	80	182
M3	71	60	176
M4	83	68	165
M5	33	66	171
M6	44	69	167
Mean	60	65	171
SD	16	9	6

**Table 3.** Comparison of the temporal parameters of gait during stair ascending and descending in healthy control subjects and patients.

	ascent						descent					
	control		pathological		healthy		control		pathological		healthy	
	subjects		limb		limb		subjects		limb		limb	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
stride time (s)	1.4	0.16	1.4	0.19	1.4	0.2	1.23	0.18	1.14	0.2	1.2	0.2
			p=0.89						p=0.64			
% support	69	2	68	2	69	1	63	2	62	4	63	2
			p=0.21						p=0.31			
% swing	31	2	32	2	31	1	38	2	38	4	37	2
			p=0.22						p=0.36			

P values: Kruskal Wallis test

**Table 4.** Comparison of hip movements during stair ascending and descending in healthy control subjects and patients (unit: degrees). Negative values indicate adduction.

movements	phase	ascent phase						descent phase					
		control subjects		pathological limb		healthy limb		control subjects		pathological limb		healthy limb	
		mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
abd/add	heel contact	3	4	4	5	5	7	-4	4	-4	3	-6	4
				p=0.80				p=0.58					
	toe off	-4	3	-4	3	-5	5	-3	3	0	3	-3	5
				p=0.94				p=0.21					
	clearance	1	3	3	5	0	7	-3	3	-1	4	-3	5
			p=0.74				p=0.97						
	RoM	12	5	14	4	15	3	10	2	11	3	11	3
				p=0.61				p=0.69					
flex/ext	heel contact	55	5	56	6	53	6	17	5	16	7	14	6
				p=0.71				p=0.52					
	toe off	23	4	22	9	21	7	20	4	17	7	17	7
				p=0.61				p=0.62					
	clearance	49	5	47	9	46	6	29	4	27	8	27	8
			p=0.65				p=0.50						
	RoM	55	5	54	6	55	6	26	2	28	6	26	5
				p=0.90				p=0.64					

P values: Kruskal Wallis test

**Table 5.** Comparison of pelvis position during stair ascending and descending in healthy control subjects and patients (unit: degrees).

Negative values indicate inclination to the left, counterclockwise rotation and backward tilt.

Movement	phase	ascent phase						descent phase					
		control subjects		pathological limb		healthy limb		control subjects		pathological limb		healthy limb	
		mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
Inclination	heel contact	4	2	7	4	4	4	-3	3	-3	3	-5	3
	toe off	-2	2	-2	4	-4	4	0	2	3	3	-4	4
	clearance	3	2	3	4	1	5	0	2	2	4	1	5
	RoM	12	4	14	2	15	2	6	3	8	3	15	2
Rotation	heel contact	-1	4	-1	6	-5	4	2	4	4	4	0	4
	toe off	2	3	2	5	1	4	1	2	2	5	-2	4
	clearance	-1	3	-1	6	-2	3	1	3	2	5	-2	3
	RoM	11	4	12	5	13	6	7	3	8	3	9	3
Tilt	heel contact	0	4	4	3	2	5	-2	4	0	3	-1	3
	toe off	6	3	8	5	9	4	-2	4	-1	3	-1	2
	clearance	6	3	7	4	8	4	-1	4	0	3	-1	3
	RoM	6	2	5	1	8	3	5	1	5	2	5	2

P values: Kruskal Wallis test; \* significant difference,  $p < 0.05$ ; post hoc Mann Whitney test; control subjects vs. pathological limb:  $p = 0.012$

## Figure legends

**Figure 1:** Marker position: paired markers (right and left):1-3, tragi; 4-6, acromion; 7-9, olecranon; 8-10, styloid process of the ulna; 11-13, anterior superior iliac spine; 14-15, greater trochanter; 16-17, lateral epicondyle of the femur; 18-19, lateral malleolus; midline: 2, glabella, 12, spinous process of S1.

**Figure 2:** Stairs structure used in the study.

**Figure 3:** Knee flexion-extension during the three phases of stairs ascent and descent.

**Figure 4:** Anterior-posterior and medio-lateral CoM displacement during stairs ascent and descent.

Figure 1  
[Click here to download high resolution image](#)

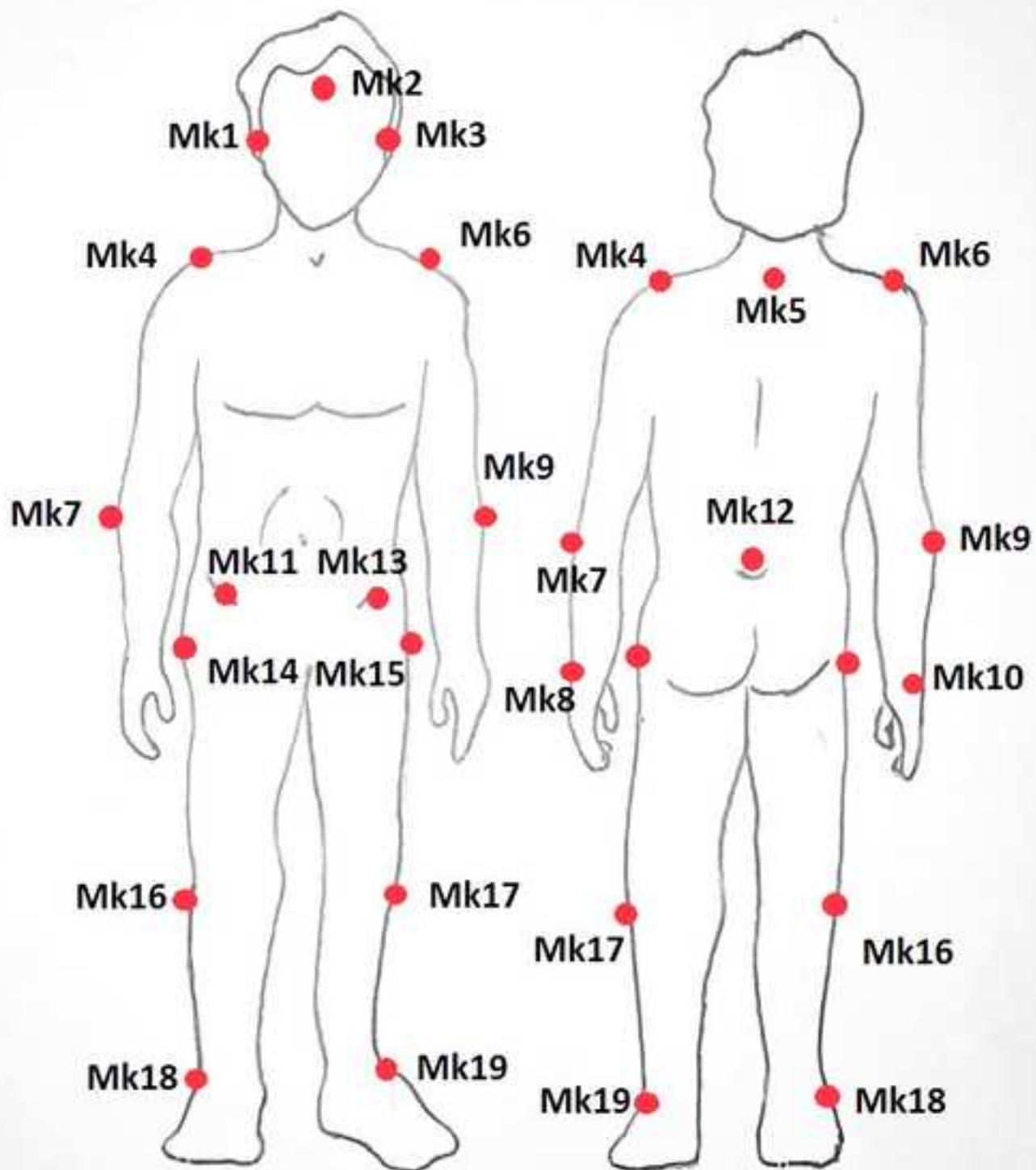


Figure 2  
[Click here to download high resolution image](#)

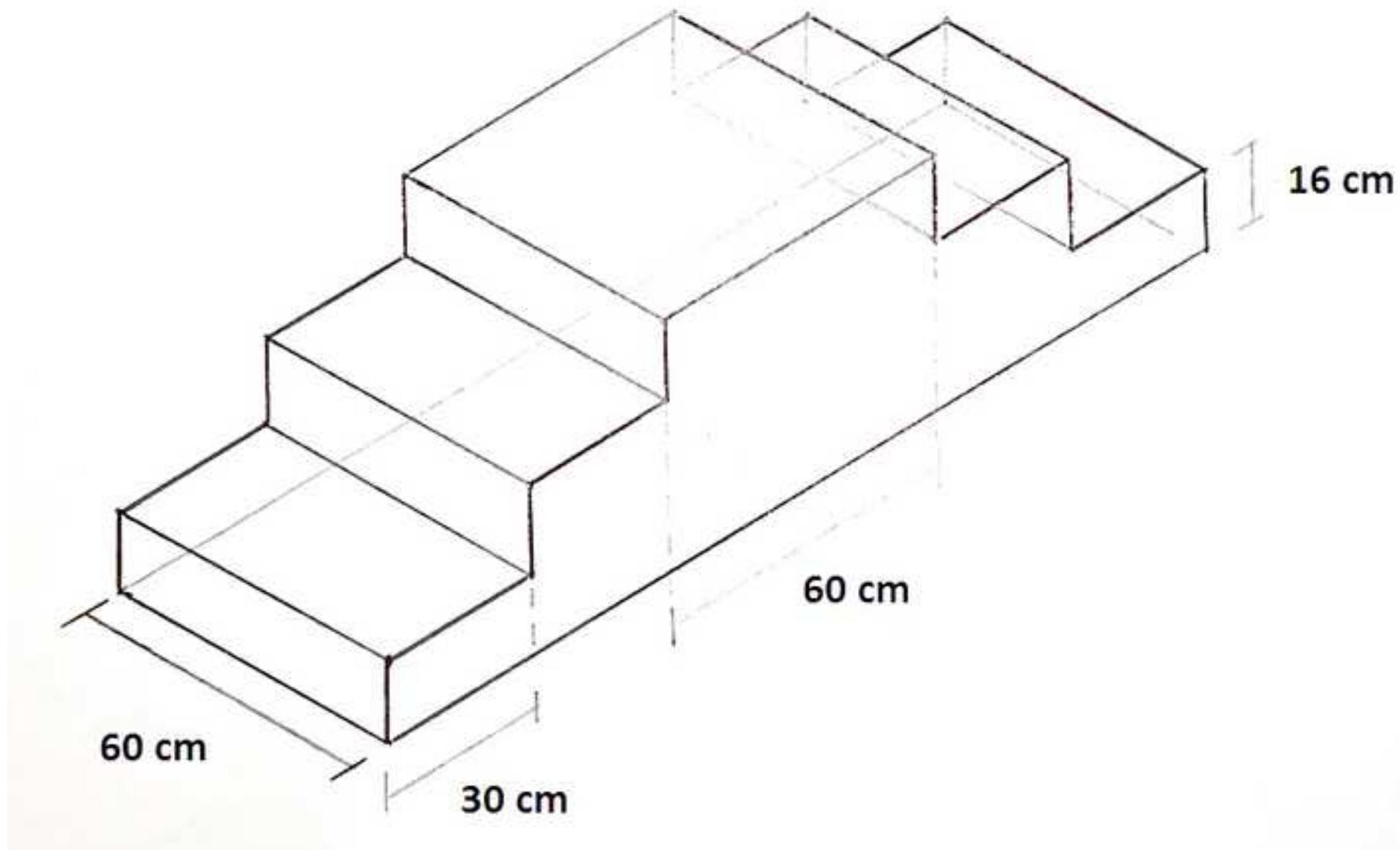


Figure 3  
[Click here to download high resolution image](#)

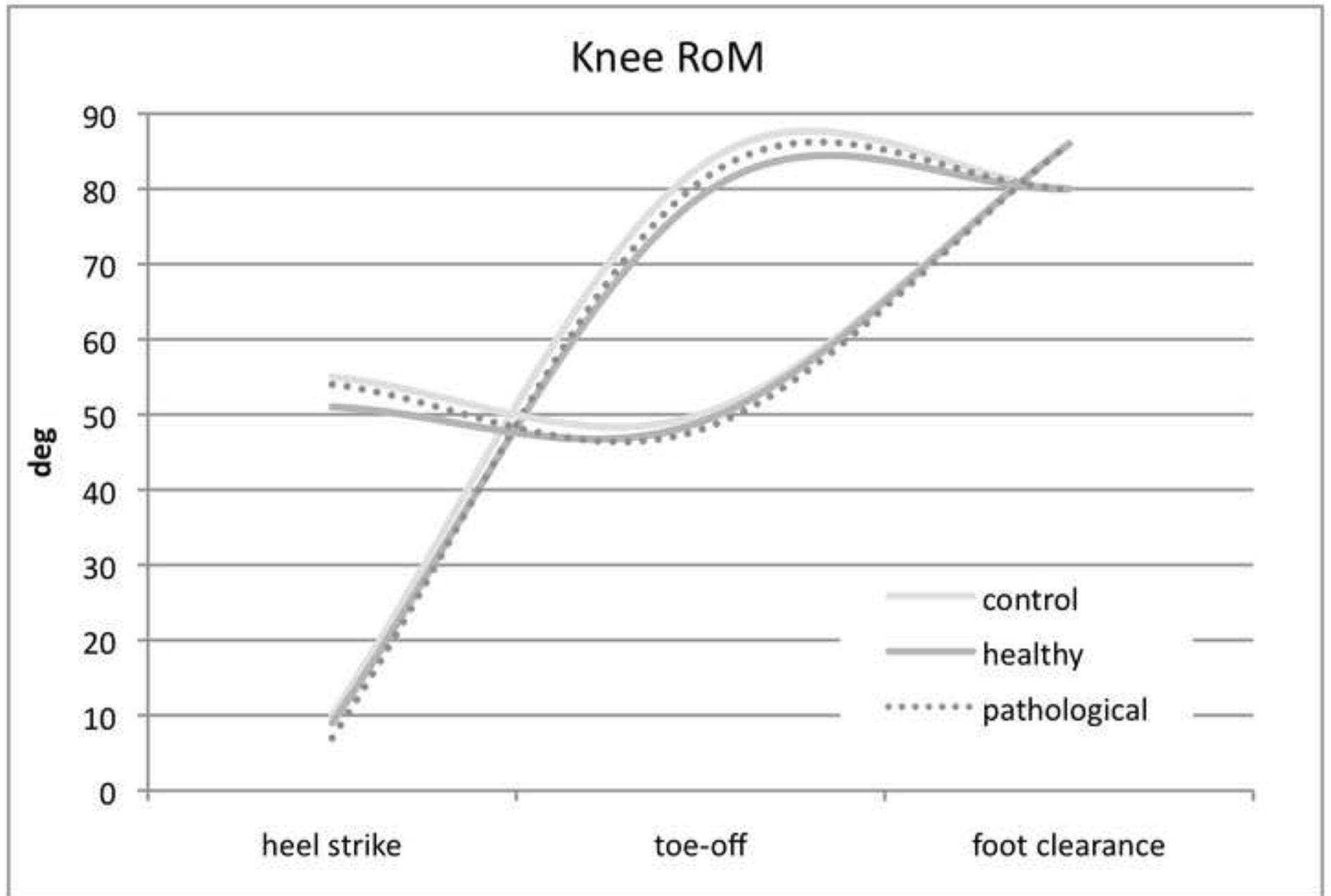
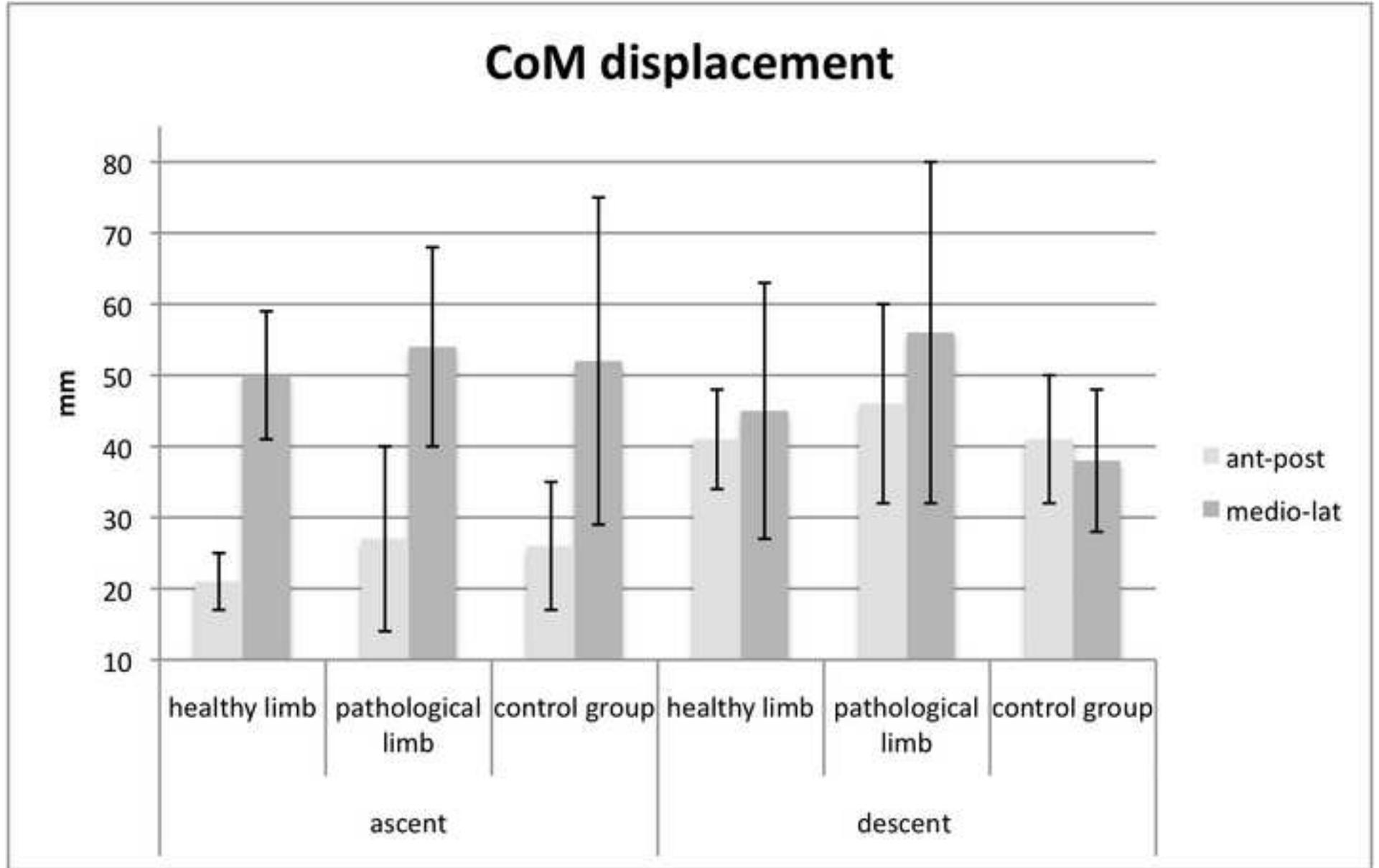


Figure 4  
[Click here to download high resolution image](#)



AMERICAN ASSOCIATION OF ORAL AND MAXILLOFACIAL SURGEONS

# Financial Relationships Disclosure Form

## For Faculty, Authors, Committee/Board Members, Reviewers and Staff

Organizations accredited by the American Dental Association Continuing Education Recognition Program (ADA CERP) and Accreditation Council for Continuing Medical Education (ACCME) are required to identify and resolve all potential conflicts of interest with any individual in a position to influence and/or control the content of CDE/CME activities. A conflict of interest will be considered to exist if: (1) the individual has a *'relevant financial relationship'*; that is, he/she has received financial benefits of any amount, within the past 12 months, from a *'commercial interest'* (an entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients), and (2) the individual is in a position to affect the content of CDE/CME regarding the products or services of the commercial interest.

All individuals in a position to influence and/or control the content of AAOMS CDE/CME activities are required to disclose to the AAOMS, and subsequently to learners: (1) any relevant financial relationship(s) they have with a commercial interest, or (2) if they do not have a relevant financial relationship with a commercial interest.

Failure to provide disclosure information in a timely manner prior to the individual's involvement will result in the disqualification of the potential Faculty, Author, Committee/Board Member, or Staff, from participating in the CDE/CME activity.

Type of CME activity: JOMS Manuscript Submission

Title of Submission: Stair ascent and descent: a daily task to investigate donor site morbidity following osteocutaneous free fibula transfer

Name: Chiarella Sforza Date: 01 May 2014

Please check one to indicate your role:

Faculty     Author     Committee Member (specify: \_\_\_\_\_)     Board of Trustees  
 Reviewer     Staff     Other (specify: \_\_\_\_\_)

E-mail(required):

chiarella.sforza@unimi.it

**DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM**

**NO**-Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**OR**

**YES**-I have or  an immediate family member has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The financial relationships are identified as follows (if needed, attach an additional list):

**RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)**

Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	Research Grant (including funding to an institution for contracted research)	Speakers' Bureau	Stock/Bonds (excluding Mutual Funds)	Consultant	Other (Identify)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I affirm that the foregoing information is complete and truthful, and I agree to notify the AAOMS immediately if there are any changes or additions to my relevant financial relationships. During my participation in this activity, I will wholly support the AAOMS' commitment to conducting CDE activities with the highest integrity, scientific objectivity, and without bias. I agree that I will not accept any honoraria, additional payments or reimbursements beyond what has been agreed upon to be paid directly by the AAOMS in relation to this educational activity.

Electronic Signature\*:



Date: 01 May 2014 **Corresponding author**

*\*Electronic signature required from **corresponding author only**. It is the responsibility of the corresponding author to collect and submit all relevant conflicts of interest (or lack thereof) of all contributing authors at the time of the submission.*

\_\_\_ 1<sup>st</sup> Co-Author (if applicable)  
 Name: Alessandro Baj \_\_\_\_\_

**DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM**

\_\_\_X\_\_\_ **NO**—Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**OR**  
 \_\_\_ \_\_\_ **YES**—I have or \_\_\_ an immediate family member has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The financial relationships are identified as follows (if needed, attach an additional list):

Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)				
	Research Grant (including funding to an institution for contracted research)	Speakers' Bureau	Stock/Bonds (excluding Mutual Funds)	Consultant	Other (Identify)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\_\_\_ 2<sup>nd</sup> Co-Author (if applicable)  
 Name: \_\_\_ Nicola Lovecchio \_\_\_\_\_

**DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM**

\_\_\_X\_\_\_ **NO**—Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**OR**  
 \_\_\_ \_\_\_ **YES**—I have or \_\_\_ an immediate family member has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The financial relationships are identified as follows (if needed, attach an additional list):

Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)				
	Research Grant (including funding to an institution for contracted research)	Speakers' Bureau	Stock/Bonds (excluding Mutual Funds)	Consultant	Other (Identify)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\_\_\_ 3<sup>rd</sup> Co-Author (if applicable)  
 Name: \_\_\_ Alessandro Bolzoni \_\_\_\_\_

**DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM**

\_\_\_X\_\_\_ **NO**—Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**OR**  
 \_\_\_ \_\_\_ **YES**—I have or \_\_\_ an immediate family member has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The financial relationships are identified as follows (if needed, attach an additional list):

Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)				
	Research Grant (including funding to an institution for contracted research)	Speakers' Bureau	Stock/Bonds (excluding Mutual Funds)	Consultant	Other (Identify)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<input type="checkbox"/>					
<input type="checkbox"/>					

\_\_\_ 4<sup>th</sup> Co-Author (if applicable)  
 Name: Andrea Mapelli

**DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM**

X \_\_\_ **NO**—Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**OR**

\_\_\_ **YES**—I have or \_\_\_ an immediate family member has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The financial relationships are identified as follows (if needed, attach an additional list):

RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)					
Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	Research Grant (including funding to an institution for contracted research)	Speakers' Bureau	Stock/Bonds (excluding Mutual Funds)	Consultant	Other (Identify)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\_\_\_ 5<sup>th</sup> Co-Author (if applicable)  
 Name: Aldo Bruno Gianni \_\_\_\_\_

**DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM**

X \_\_\_ **NO**—Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**OR**

\_\_\_ **YES**—I have or \_\_\_ an immediate family member has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The financial relationships are identified as follows (if needed, attach an additional list):

RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)					
Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	Research Grant (including funding to an institution for contracted research)	Speakers' Bureau	Stock/Bonds (excluding Mutual Funds)	Consultant	Other (Identify)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\_\_\_ 6<sup>th</sup> Co-Author (if applicable)  
 Name: \_\_\_\_\_

**DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM**

\_\_\_ **NO**—Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**OR**

\_\_\_ **YES**—I have or \_\_\_ an immediate family member has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The financial relationships are identified as follows (if needed, attach an additional list):

RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)					
Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	Research Grant (including funding to an institution for contracted research)	Speakers' Bureau	Stock/Bonds (excluding Mutual Funds)	Consultant	Other (Identify)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<input type="checkbox"/>					
<input type="checkbox"/>					