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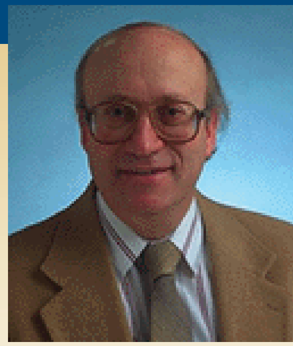

NIST Medical Phantom Device to Assist with the Calibration and Performance Testing of CAOS Systems

Introduction

Sources indicate that 8.8% of revision hip surgery could be attributed to malpositioning of the implant (Heck D.A., 2006; Malchau H., 2002). This includes dislocation (5.8%) and technical error (3.0%). A revision orthopaedic surgery is significantly more risky and painful than the original operation. The total number of revision hip and knee replacement surgeries in the U.S. in 2005 was ~18,285 (HCUPnet/AHRQ). The 8.8% of these revision surgeries amounts to 1,609 operations. Since the cost of a revision surgery is ~$45,621 (Heck D.A.), the total cost of these revision operations was $73,407,838. It is natural that people started looking into the use of new technologies like Computer Assisted Surgery (CAS) to reduce implant malpositioning.

In the early 1980s a group of National Institute of Standards and Technology (NIST) researchers modified an athlete tracking sensor (Selspot, manufactured by SELCOM[1]) for use in robot calibration and performance measurements (Dainis A., 1985). Extensive study was performed on measurement errors of this sensor and its controller. This sensor became a commercial product used by manufacturers and users of Industrial Robots (IRs) for robot calibration and performance measurements for the last 20 years. In the early 1990s, this type of sensor was used for precision enhancement in spine surgery (Nolte L.P., 1995). Spine surgery tools were equipped with probes holding three or more target Light Emitting Diodes (LEDs), tracked by the sensor, which can now determine their position and orientation. A Dynamic Reference Base (DRB) coordinate frame equipped with three or more target LEDs was attached to the vertebra undergoing surgery. Appropriate mathematical transformations converted the surgical tools' position and orientation coordinates to DRB frame coordinates, thus facilitating insertion of screws at the right position and orientation in the overwhelming majority of cases. Around the same time spine surgeries were performed using a similar tracking sensor system (Lavallee S., 1995). Lavallee experimented with surface registration for the identification of characteristic bone landmarks instead of simple point registration. He also experimented with a robot carrying a laser beam for surgical drill tool alignment. Soon these techniques were extended to total hip and knee arthroplasties, and the field of Computer Assisted Orthopaedic Surgery (CAOS) was born.

The market for use of CAOS systems inside the operating room has evolved significantly from the original Selspot system. Selspot used two lateral effect photodiode camera tracking sensors, while most modern CAOS systems use two or three Charge Coupled Device (CCD) cameras with active LED targets or passive sphere targets illuminated by infrared light. Comparison of conventional vs. CAOS arthroplasty procedures has demonstrated that CAOS systems show significant improvement in the desired surgical result. In particular, CAOS systems help reduce the variability of positioning of prosthetic components, thus permitting a more consistent placement (Haaker R.G.A., 2007, Nogler M., 2004).

Users of CAOS systems began to recognize that tracking sensors had accuracy problems which could jeopardize surgical outcomes. The original NIST study identified several error sources. Some could still be relevant and can introduce positioning errors for the modern CAOS systems. Following is a list of these possible sources of errors:

- Camera optics
- Detector irregularities

[1] Certain commercial products and processes are identified in this paper to foster understanding. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology, nor does it imply that the products and processes identified are necessarily the best available for the purpose.

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- Target operating conditions, like temperature, non-uni form radiation field, distance from the camera sensors, etc.
- Camera position and orientation determination with respect to the tracking sensor system reference coordinate frame
- Sampling rate frequency of multiple targets

The image generated by each target on the camera tracking sensor is usually an irregular blob with non uniform intensity distribution. It falls to the controller of each tracking system to decide assignation of XY coordinates to this type of image. A simple rotation of the target, with no position change, could alter the value of the measured XY coordinates. In the case of slow sampling rate tracking systems, the target might move while its position is being sampled. The NIST study generally concluded that these tracking systems have a sweet region of low error for target positions located within 80 % of the camera detector field of view. This error increases as the target moves away from this central region.

The focus of the work reported in this paper is to address the accuracy problems associated with the use of CAOS systems by implementing well calibrated artifacts, called phantoms by most medical professionals.

Metrology Needs

The metrology needs of hip surgeries were discussed with several medical professional experts with long experience in this type of operations (See Acknowledgements following article). A workshop was organized in 2006 with a session dedicated to CAOS metrology and standards needs (Heck D.A.). Following is a summary of identified needs.

A need exists for phantoms (artifacts) that support traceability to standards organizations to confirm basic metrology. The development of standardized phantoms and testing protocols will allow development of metrics to establish validity and facilitate comparison between systems. Phantoms are required that replicate "standard" and "outlier patients." From the geometric perspective, range validation is required across the wide range of patient sizes (Short, Normal, Tall) and soft tissue perspectives (Aesthetic, Normal, Morbidly Obese). Standardized and representative anatomic referencing landmarks (fiducials) would facilitate process capability determination in the laboratory. In support of radiographic evaluation, the phantoms will need to have X-Ray absorption characteristics comparable to the range of human presentations. Standardized test environments and protocols are needed that replicate the operating room, including devices that may introduce error through mechanisms such as electro-magnetic interference. Clinical investigations to refine our understanding of device position on clinical outcomes require systems that can support large scale data retrieval in a standardized fashion. Intraoperative measurement protocols must address anatomic site, referencing approach, component positioning, navigational technologies being employed, prosthetic technologies, metadata and calibration status such that process capabilities can be established.

The first phantom was designed to address a small number of Total Hip Arthroplasty (THA) operation metrology needs for normal size adults. The Computer Assisted Orthopaedic Hip Surgery (CAOHS) phantom is designed to perform at least three performance tests relevant to THA, such as the following: 1) measure the CAOS system accuracy of the determination of coordinates of the center of rotation of the hip joint, represented by a precision magnetic ball and socket joint; 2) measure the CAOS system accuracy of moving along straight lines at distances comparable to the size of human adult large bones, along two orthogonal directions; and 3) measure the CAOS system accuracy of angular moves relevant to orthopaedic hip surgery. If the CAOHS phantoms prove useful for orthopaedic operations, similar devices will be developed for the human knee, shoulder, etc.

The First CAOHS Phantom

For best clinical results, our phantoms are designed to resemble the skeletal joint that is the subject of the operation, and suggested performance tests resemble tasks important to the actual procedure. In order to reduce fabrication and maintenance costs, we use commercially available precision parts wherever possible in phantom structure design.

The most important component of the hip joint is the ball and socket joint, which we decided to add to our phantom. Most ordinary mechanical ball and socket joints have backlash and are difficult to clean and inspect for wear because they are sealed. However, precision engineers use magnetic ball and socket joints (See Exhibit 1) and bars (See Exhibit 2), which have none of the above mentioned drawbacks and are commercially available for reasonable prices and used for the calibration and testing of precision measurement machines like Coordinate Measuring Machines (CMMs) and IRs. Furthermore, these joints can be fitted with various strength small magnets which can be selected for the proper size bar and joint orientation, so that the contact force will be sufficient to ensure that the bar will not separate from the joint socket during the test and not so large that excessive surface wear results.

Our first phantom resembles a pelvis coordinate frame, as shown in Exhibit 3, and a femur bone connected with a precision magnetic ball and socket joint, as shown in Exhibit 4. As the magnetic socket of this device is horizontal, it is called Horizontal Joint-Operating Room-CAOHS (HJ-OR-CAOHS).

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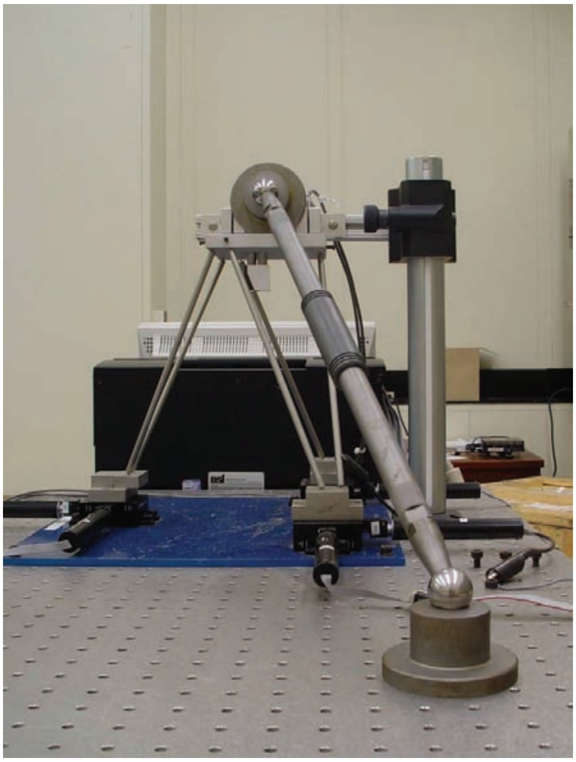
Exhibit 1: Precision magnetic ball and socket joint

Exhibit 2: Ball bar calibration test



The first HJ-OR-CAOHS phantom was fabricated a few months ago (See Exhibit 5). It is made of an L shape horizontal XY orthogonal coordinate frame, a joint horizontal mount, the magnetic ball and socket joint and a femur bar. The HJ-OR-CAOHS XY coordinate frame has small target holes (See Exhibits 6 and 7) at regular intervals of 15 mm, designed to fit the pointed probe tip of the CAOS system's target assemblies. These are plates with four or more active or passive markers which can be mounted on surgical tools. The HJ-OR-CAOHS also has two larger holes for the mounting of DRB target assemblies. Further, the femur bar features two larger holes for mounting of DRB target assemblies which can be used to determine the coordinates of the ball center of rotation. The tips of all HJ-OR-CAOHS phantom bars are machined to

Exhibit 3: CAOHS phantom coordinate frame superimposed on pelvis model

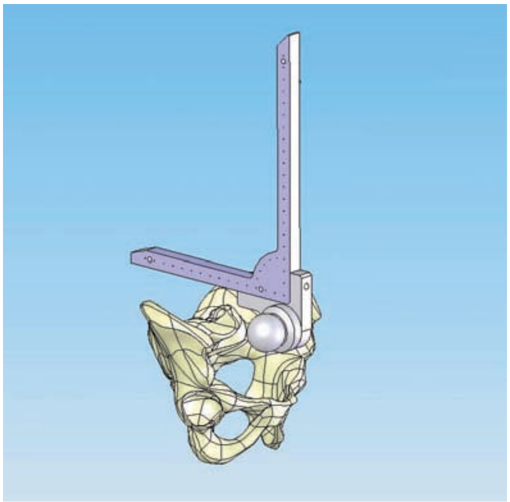


Exhibit 4: CAOHS phantom coordinate frame and femur bar connected with magnetic ball and socket joint

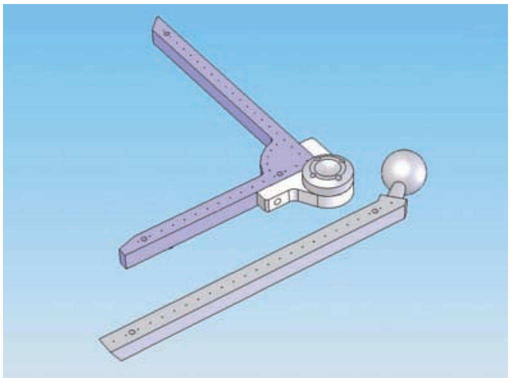


Exhibit 5: The first prototype of the HJ-OR-CAOHS phantom

Exhibit 6: Cross section view of target hole

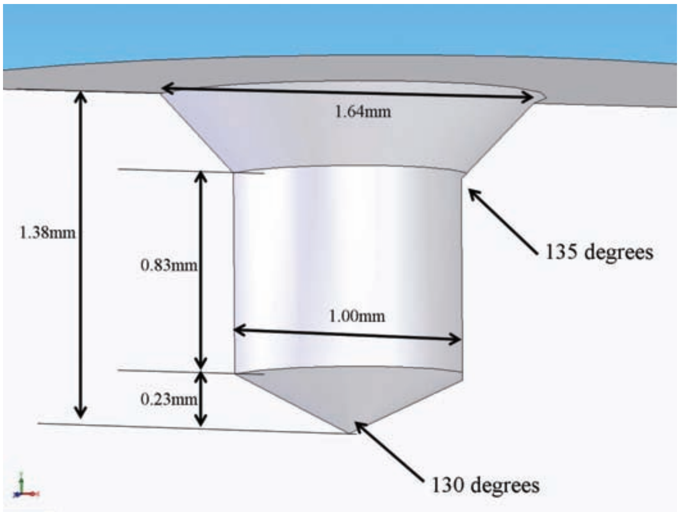
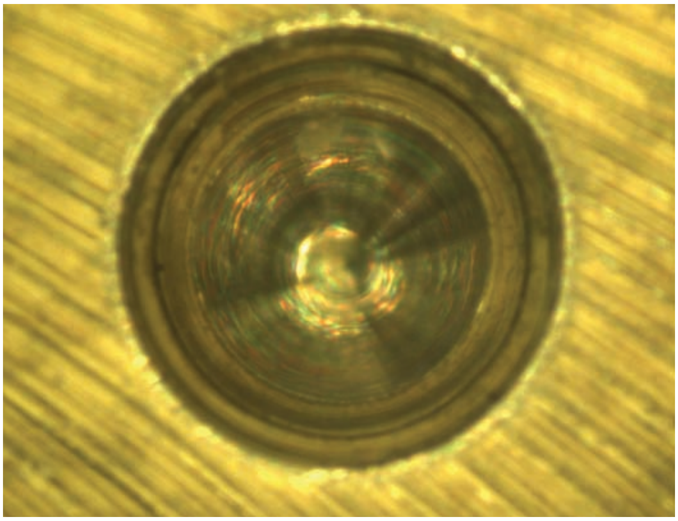


Exhibit 7: Microscopic image of target hole



form various angles, useful for hip arthroplasty procedures (See Exhibits 8 and 9). An arc at the base of the coordinate frame has been fitted with target holes spaced at regular angular increments, offering additional angular calibration and testing capability (See Exhibit 10). The magnetic ball and socket joint are commercially available and made of stainless steel, while the rest of the parts are made of Invar for better thermal stability inside the operating room.

Exhibit 11 shows the L shape XY coordinate frame with its target holes marked X_1 to X_{20} on the X axis (horizontal in the

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Exhibit 8: Angles between adjacent planes in figure can be used for evaluation of surgical cutting tools

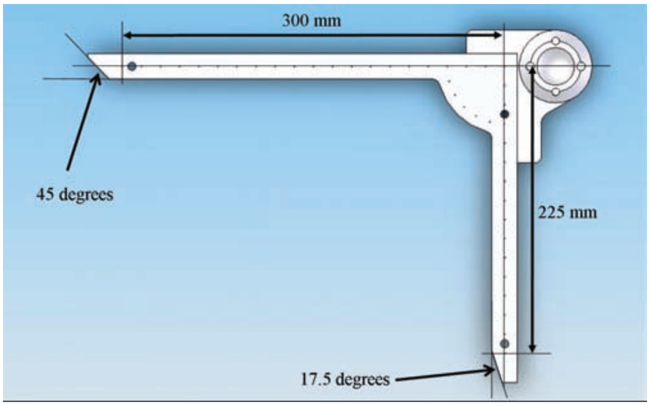


exhibit) and Y_1 to Y_{15} on the Y axis (vertical in the exhibit). The nominal incremental distance between these target points is 15 mm, which gives a nominal X axis length of 300 mm and nominal Y axis of 225 mm (See Exhibit 8). The X axis is longer because it is intended to approximate the length of an adult femur bone. The distance between any two target holes is measured between the tips of the two holes. Although the nominal distance can be calculated assuming a nominal increment of 15 mm, between neighboring holes, the actual distance is determined through careful calibration to be described in a future paper.

Exhibit 9: Femur bar showing two angled planes and DRB mount holes

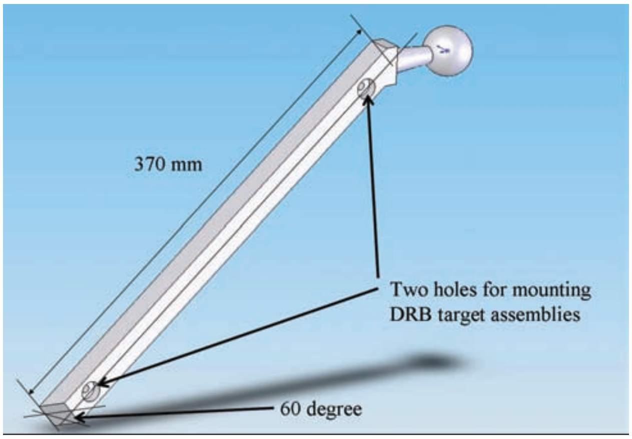
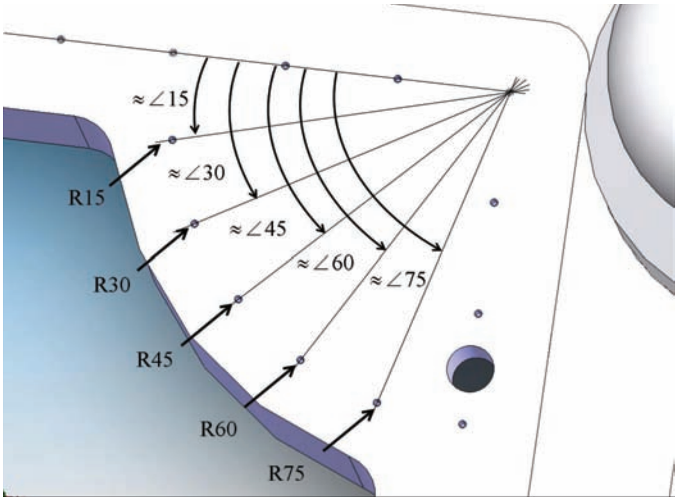


Exhibit 6 shows the nominal dimensions of target holes.

Exhibit 10: The origin arc with the target holes defining certain angles with respect to the X coordinate axis



Special attention was given to the drilling of these holes in order to achieve smooth, clean hole walls and tip and hole axis, which is nominally orthogonal to the corresponding coordinate frame XY axes. Several drill bits were used and each was not used for more than four holes. Every one of the target holes was examined and photographed under a microscope. One concern was the presence of burrs, which could prevent the tip of the CAOS system target probe from reaching the tip of the target hole. Exhibit 7 shows a typical microscope hole image, revealing that the hole tip is really a hemispherical surface and not a sharp tip as Exhibit 6 implies. It is thus important that during CAOS testing the pointed probe tip of the CAOS system target assemblies can reach that hemispherical surface and not be able to move laterally by any significant amount as that motion will introduce measurement errors.

The HJ-OR-CAOHS phantom offers two different options for testing the ability of a CAOS system to measure angles. One may involve the use of the saw blade, spatula or other similar tool and the other the pointed probe tip of the CAOS system target assemblies. The end planes of all the phantom bars are shaped to form angles commonly used during hip procedures. From Exhibit 8 it can be seen that the X axis bar of the phantom coordinate frame terminates at a nominal 45° angle, considered by many orthopaedic surgeons as the best choice for the

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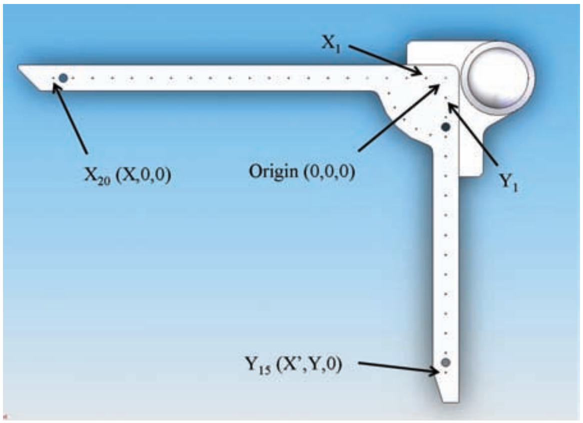
Exhibit 11: The L shape XY coordinate frame with the target holes



hip acetabulum prosthesis inclination angle. The Y axis bar of the phantom coordinate frame terminates at a nominal 17.5° angle, considered by many as the best choice for the hip acetabulum prosthesis anteversion angle. The femur bar terminates at a nominal 60° angle, preferred by many for decapitation of the damaged head of the femur bone. The arc around the origin of the coordinate XY frame axes has five target holes at nominal angles of 15°, 30°, 45°, 60° and 75° with respect to the X axis. These are three point angle measurements that allow pointed probe tip measurement tests.

NIST staff have calibrated all critical features on the HJ-OR-CAOHS using an industrial grade CMM. These features include target hole locations and the center of rotation. In all cases, the expanded uncertainty U with k = 2 in the determination of the three dimensional coordinate is less than 0.08 mm. A future publication will report on calibration procedures and an additional publication will describe results of industrial testing. Coordinates of the ball center of rotation are measured with respect to the CMM reference coordinate frame. Using coordinate transformation algorithms similar to those used for calibration of IR work cells, it is possible to refer these coordinates to the HJ-OR-CAOHS phantom coordinate frame, thus making use of the phantom independent of the metrology instrument used for its calibration.

A new version of the OR-CAOHS with an angled magnetic ball and socket joint similar to that of a human pelvis is also being designed.

Material Selection

The magnetic ball and socket joint parts were commercially available and cost approximately $130 each. The socket was a 1.5" Tooling Monument from ATT Metrology Services[1] made of stainless steel material. The ball was a 1.5" threaded ball from Precision Balls[1] made of 440C hardened stainless steel material, which is strongly attracted by a magnetic field.

Five materials, listed below, were considered for the fabrication of the L shape XY coordinate frame, the femur bar and the ball and socket mount.

Five materials, listed below, were considered for the fabrication of the L shape XY coordinate frame, the femur bar and the ball and socket mount. The main deciding factors, which were considered, were the cost, the material density and the expansion $Dl_{0.3m}$ ffor an artifact length of 0.3 m and 5°C temperature variation. The material properties were obtained from MatWeb.

Aluminum 6061. Density = 2.7 g/cm^3
Coefficient of Thermal Expansion = 23.6 µm/m-°C
$Dl_{0.3m}$ = **0.035 mm**

AISI 1020 Steel. Density = 7.872 g/cm^3
Coefficient of Thermal Expansion = 11.7 µm/m-°C
$Dl_{0.3m}$ = **0.017 mm**

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AISI 440 Stainless Steel. Density = 7.8 g/cm^3
Coefficient of Thermal Expansion = 10.2 μm/m-°C
$Dl_{0.3m}$ = **0.015 mm**

Titanium Ti-6Al-4V. Density = 4.43 g/cm^3
Coefficient of Thermal Expansion = 8.6 μm/m-°C
$Dl_{0.3m}$ = **0.012 mm**

Invar 36. Density = 8.05 gr/cm^3
Coefficient of Thermal Expansion = 1.3 μm/m-°C
$Dl_{0.3m}$ = **0.001 mm**

Aluminum is inexpensive, easy to machine and lightweight, but has a $Dl_{0.3m}$ of 0.035μm which might not be acceptable for some applications. Another problem with Aluminum might be excessive wear of the target holes with frequent insertions of pointed probes. Because our prototype phantom device will be used for research we decided to use Invar, which is heavier, more expensive and more difficult to machine than aluminum, but we will not have to worry about thermal stability and wear.

Conclusions

We have described the design of a phantom which may be used for measuring performance of CAOS systems inside operating rooms. This phantom can also be used for the calibration of CAOS systems. Calibration is, of course, primarily the responsibility of the manufacturer of CAOS systems and can be performed after fabrication and during servicing operations.

We have designed and fabricated a horizontal joint computer assisted orthopaedic hip surgery phantom. This device appears to be working very well and was recently calibrated and sent to a medical research group for testing. Calibration and testing results will be reported in future publications.

Acknowledgements

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SELCOM, Partille, Sweden (presently owned by LMI Technologies), www.lmint.com

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