Improving safety in operating room: design and experimentation of a RFId-based medical device for surgical sponges management

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***Abstract* – In this paper the authors intend to present an application of radio frequency identification technology (RFID) in health care, with the aim to improve clinical safety in operating room. It was designed and built a prototype for counting sponges during surgery. The presented system, following in vitro and in vivo tests, has allowed to obtain very good results in terms of detection of the gauze in the abdomen of the patient and, in general, in management of them during the clinical practice.**

I. Introduction

Retained surgical sponges inside a patient following surgery is a rare but critical event leading to severe clinical, economic and social consequences.

Hospitals have been urged to develop strict protocols to count sponges in order to track items during surgery and to prevent errors. Operating teams still perform count manually but this procedure is extremely liable to error.

The introduction of X-ray detectable sponges contributed to reducing incidence of these cases, however, these systems do not allow prevention of the event.

.II. Materials and Method

In order to make a reliable automated process and to reduce time for counting, as well as to locate the sponge in the patient's abdomen, our team has designed, developed and tested a system which provides to the use of sponges with RFID tags detectable by remote reading (Fig. 1)

Fig. 1: tagged surgical sponge and insertion of tag

The system designed consists of:

a) an antenna for the initial counts of sponges;
b) an antenna for the counts of used sponges;
c) an antenna for the localization of the sponge in patient;
d) sponges fitted with RFID tags.
e) a management software: in continuous communication with readers, it provides to identification and counting of surgical sponge, showing real-time count and supporting clinicians in surgical sponges management.

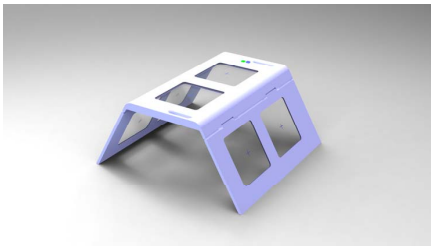

Fig. 2: Antenna for localization in patient's body

Fig. 3: antennas

Figura 4 - management software screenshoot

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In particular, the tags used for this experiment:

a) are small to allow integration in surgical sponges. In particulary, the sponges are hand-sewn and a pocket is formed in one of the corners to put the tag (Fig. 1);
b) are resistant to high temperatures, to keep them intact and properly functioning on sterilization;
c) have good mechanical strength, with particular reference to impact, to allow a safe handling of the sponge;
d) have high resistance to chemical and biological fluids;
e) are manifactured with biocompatible material.

After several tests, for the realization of the prototype, we chose High Frequency (13.56 MHz), due to:

a) the presence of technical standards applicable in healthcare;
b) the optimal reading range in biological environment.

The method identified to proceed to the counting of laparotomic sponges, provides that a reader is bring near the tagged sponges, allowing a count of the total number of them at the beginning of the surgery and that, at the end of surgery, the reader is bring near the container with used sponges (Fig. 3) and near to not used sponges.

In the case where there is a discrepancy in the control done on the number of sponges, an antenna will be used to find the area of the body of the patient in which the laparotomy sponge has been retained (Fig. 2).

The management software supports the staff in the identification in real time of position of the sponges.

An important stage in the design of the prototype, was concerning to risk assessment, analysing and reduction.

III. TEST

After an initial phase of analysis to identify the best configuration tag/antenna in terms of reading distances, biocompatibility, size and radiated power, the system has been evaluated in experimental tests in vitro and in vivo.

In vitro test

Preliminary in vitro tests have allowed us to assess the efficiency of the system, as well as to improve the device's ergonomy.

The first tests were carried out by positioning the antenna on the operating table so that this one was not contained in the volume of detection of the antenna system. It was then tested the goodness of the system through the use of a single tag and it was observed that the presence of the operating table does not affect system performance.

The tests have shown a certain detection of tagged sponges, even with the interposition of the body.

It was then tested the detection of multiple tagged sponges (up to a maximum of three), randomly crumpled; also in this case the sponges have always been identified, recognizing them as distinct through their identification number shown by the software used.

To verify that the devices eventually present during this phase in the OR (usually post-procedure) did not influenced the system and, conversely, the system does not interfere with the proper functioning of devices, the tests were also conducted by monitoring the "patient".

A final situation tested was the presence of metallic agraphes that can be found in the site of surgery, following previous anastomosis through surgical staplers. We found no interference.

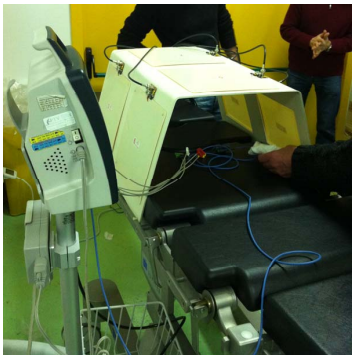

FIG. 5: IN VITRO TEST

In vivo test

Subsequent tests were conducted at the Station for Animal Technology (STA) of the University of Rome Tor Vergata. The experiment was conducted on a pig, the animal model among the most used among the higher mammals, for the purposes of the trial.

Pig, in fact, is an animal which is genetically close to the human species, also including the type of diet (omnivorous), the anatomy and physiology of the digestive system are similar to those of humans. Is therefore conceivable that the results of experiments carried out on pigs are movable, with appropriate correction factors, to the human species.

Through a laparotomy, we've inserted tagged sponges in different anatomical sites (external or internal) or by placing sponges individually or overlapping them, in order to test the anti-collision protocol.

We performed 6 different tests, listed below.

1. First test

We have included a total of 5 sponges in 5 different anatomical sites distant from each other, in particular:

a) No. 1 in the right iliac fossa;
b) No. 1 in the left iliac fossa;
c) No. 1 in the right hypochondrium;
d) No. 1 in the left hypochondrium;
e) No. 1 in the root of the mesentery.

2. Second test

We have included a total of 5 sponges in 3 different anatomical sites distant from each other:

a) No. 2 pelleted in the pelvis;
b) No. 2 pelleted in the diaphragm;
c) No. 1 in the root of the mesentery.

3. Round three

We have included a total of 5 sponges in 3 different anatomical sites distant from each other:

a) No. 2 pelleted in the pelvis;
b) No. 2 pelleted in the diaphragm;
c) No. 1 placed under the pig but externally to it.

4. Fourth test

We have included a total of 5 sponges placed all in the pelvis (No.3 with tag sewn together overlapping, No. 2 overlapping but not sewn)

5. Fifth test

We have included a total of 7 sponges put all in the pelvis (No. 5 stitched together with overlapping tags, No.2 overlapping but not sewn).

6. Sixth round

We have included a total of 6 sponges placed on a table. This test was repeated No. 2 times.

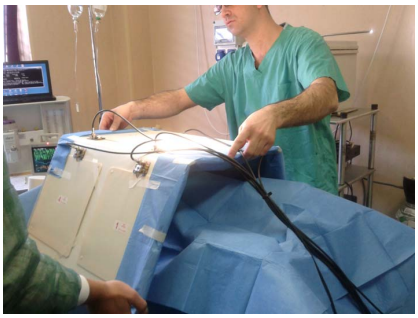

FIG. 6: IN VIVO TEST

IV. RESULTS AND CONCLUSIONS

The experimentation has led to obtain satisfactory results with respect to efficiency and repeatability of the measurements, reporting neither false positive nor false negative.

The prototype has correctly identified the number of sponges present both in vitro and in vivo test; the results are more than acceptable even in not realistic operating conditions or with extremely low probability of occurrence.

The results obtained allow to conclude that the prototype will allow to obtain a significant risk reduction in surgical practice; in particular the device allows a time reduction in sponges count as well as an improvement of the count accuracy.

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