

The advantages of a single use retractor for soft tissue protection in direct anterior approach total hip arthroplasty: the preliminary experience

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Abstract. The anterior hip approach is a procedure with increasing popularity in hip replacement surgery due to its many benefits and the number of surgeons using it is steadily increasing around the world. Less pain, better results in the first few weeks, reduced dislocation rate are the prerogatives of this approach. We analyzed in a group of 26 patients the use of a soft tissue retractor, Alexis Orthopedic Protector, the CPK values in the first third and fifth postoperative day. The results obtained, normalized, demonstrate a slight reduction in tissue damage using the device compared to a control group. In addition to blood values, improved exposure, distribution of leverage, cleanliness of the field and a potential reduction in infectious risk are advantages for the use of an orthopedic surgery retractor. We believe that the adoption of the Alexis Orthopedic Protector provides numerous improvements during the hip arthroplasty surgical procedure, especially when adopting the direct anterior approach, because it distributes the traction forces around the surgical path resulting in greater visibility. However, the small number of patients is not sufficient to perform an accurate statistical analysis and further studies on larger samples will be required. (www.actabiomedica.it)

Key words: soft tissue protection, retractor, anterior approach, hip arthroplasty

Introduction

Firstly described in 1883 by Heuter for the treatment of tubercular abscesses, then described again in early 1900s by Smith-Petersen and by Judet and Judet (1) and returned popular in the early 2000s (2), the anterior approach to the hip (DAA) for hip arthroplasty has become more and more popular over the years thanks to the several advantages it provides to the patient. In fact, thanks to its muscle sparing features it is believed to have a lower rate of complications. In 2011, 10% of surgeons interviewed at The annual meeting of the American academy of orthopedic surgeons and at EFORT chose the DAA for hip replacement (3), while the Italian Arthroplasty Registry reported 15.9% of implants performed with DAA in 2020 and the Australian Registry reported 27.53%

of implants performed with DAA. The increased popularity of DAA among surgeons is due to the advantages that this approach provides compared with other approaches.

In particular, it shows earlier recovery after THA compared to posterior approach (4,5), with shorter length of stay and higher hip functional scores at 6 weeks. Moreover, it is associated with lower dislocation rate (6) and with less consumption of narcotics and less post-operative pain (7).

Compared to direct lateral approach, the surgical procedure performed with DAA is slightly longer but it shows lower perioperative blood loss and transfusions (8). Moreover, MRI studies (9) showed increased abductor tears, trochanteric fluid collections and gluteus medius tendinosis in the direct lateral approach group.

However, the inadvertent lesion of rectus femori or the tensor fasciae latae might cause a lower patient satisfaction post-operatively and certain degrees of post-operative pain.

To avoid these complications we evaluated the possibility of implementing our surgical technique with a soft tissue protector, in particular the Alexis Orthopaedic Protector (Applied Medical Resources Corporation, Rancho Santa Margarita, CA), and to evaluate its efficacy in soft tissue shielding through serum creatine kinase.

Materials and methods

In a high-volume hip prosthetic surgery center, over 400 procedures per year, we considered 50 patients undergoing anterior hip prosthetic surgery. All surgical procedures were performed by the same senior surgeon with an experience of about 150 interventions / year through DAA without the help of a traction table or a mechanical positioner and with the same anesthetic protocol of loco-regional anesthesia and sedation. Serum creatine phosphokinase (CPK) was dosed in the 1st-3rd-5th post-operative day. For our analyses, we utilised the coding language Python 3.8.3. The t-test was performed in order to evaluate the difference between the relative values at 3 and 5 days post-operatively in the two groups. We have selected only the patients in which we have performed the collection of the blood sample in our hospital to have the same evaluation criteria. The functional evaluation was not performed in this study and we did not analyze the perioperative VAS (Visual Analogue pain Scale) values to focus our attention only on the objective parameter of the blood CPK values to identify the effective and unbiased benefit of the device. One blind observer not involved in the surgical procedures reviewed CPK values and one blind observer not involved neither in the surgical procedure nor in the clinical follow-up performed the statistical analysis. The Alexis Orthopaedic Protector (Applied Medical Resources Corporation, Rancho Santa Margarita, CA) is a cilinder shaped retractor that shields soft tissues, including skin, fat, muscles and nerves, from the outer environment. It has two rigid or flexible rings at its edges

that help for placement, removal and to improve even traction on soft tissues. We always chose the model with rigid rings at the edges. There are also different sizes of the device according to the incision depth and length. When performing the DAA through a minimally invasive approach with oblique incision of about 8 cm long originating about 2 cm distal and lateral from anterior superior iliac spine (ASIS) oriented in line with the tensor fasciae latae (TFL) and directed towards the fibular head. The interval between TFL and sartorius is identified and entered. Then we identify and carefully cauterize the vessels and at this moment we put in place Alexis Orthopaedic Protector before placing the other Hohmann bone levers and other retractors. The remaining part of the surgical procedure takes place according to the usual steps. We remove Alexis Orthopaedic Protector just before closing the fascia, subcutaneous tissue and skin

All procedures were performed following written informed patient consent and in accordance with the ethical standards of the institutional research committee and the 1964 Declaration of Helsinki and its subsequent amendments or comparable ethical standards.

Results

The general population consisted of 40 patients, in particular 27 females and 13 males. 19 patients were affected by hip osteoarthritis, 16 were affected by femoral neck fracture and 5 were affected by aseptic necrosis of femoral head. Mean age was of 75.85 ± 7.49 years \pm for males and 75.56 ± 8.46 years old for females. The test group consisted of 26 patients, of which there were 9 males and 17 females. 17 patients were affected by hip osteoarthritis, 5 were affected by femoral neck fracture and 4 were affected by aseptic necrosis of femoral head. The mean age was 73.00 ± 6.16 for males and 74.82 ± 8.31 for females. During the follow up we lost the dosage of CPK at the 5th of 7 patients day due to patient dismissal at 4 days post-operatively. The control group consisted of 14 patients, 10 females and 4 males. 11 patients were affected by femoral neck fracture, 2 were affected by hip osteoarthritis, 1 by aseptic necrosis of femoral head. The mean age was 82.25 ± 6.65 for males and 76.80 ± 9.02 for

females. During the follow up we lost the dosage of CPK at the 5th of 3 patients day due to patient dismissal at 4 days post-operatively (Figure 1, Table 1). The statistical analysis didn't show any difference in the serum CPK level at 3 (p-value 0.77) and 5 days post-operatively (p-value 0.58), however as we can see in figure 2 there seems to be a slight difference between the test group and the control group. We didn't experience any deep surgical site infection both in the test group and in the control group. In the group treated with Alexis Orthopaedic Protector we didn't experience any superficial wound infection or suffering, while in the control group we only had one superficial wound dehiscence that healed with outpatient follow-up.

Discussion

Avoiding or reducing soft tissue harm during joint replacement surgery is one of the ambitions of modern surgery, and the use of mini-invasive surgical approaches is the first step to achieve this goal. However, mini-invasive surgery may result in excessive stretching and inadvertent damage of soft tissues while introducing in the wound surgical instruments. We strongly believe that the use of a soft tissue protector may help in reducing soft tissue injury while improving visibility for the surgeon.

Several authors studied the relationship between DAA and systemic response to the surgical procedure. Minetto et al. (10) evaluated the response through serum IL-6 measurements with evidence of high variability between individuals, while other

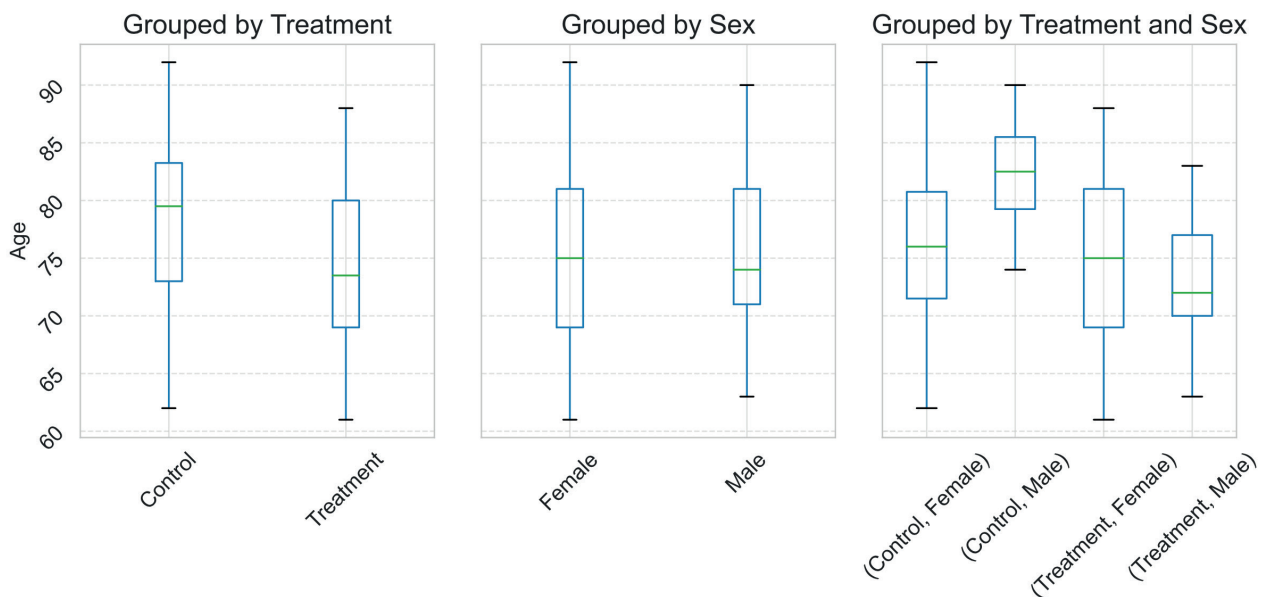


Figure 1. Patients distributions by age and divided by treatment and sex. Patients who underwent surgical procedure with the aid of Alexis Orthopedic Protector are identified as “treatment”, the control group as “control”.

Table 1. Characteristics of the patients

	Males	Females	Mean age (males)	Mean age (females)	Mean CK values 1st day (U/L)	Mean CK values 3rd day (U/L)	Mean CK values 5th day (U/L)
Treatment	9	17	73.00 ± 6.16	74.82 ± 8.31	525.16	441.92	287.75
Control	4	10	82.25 ± 6.65	76.80 ± 9.02	501.69	395.00	325.30

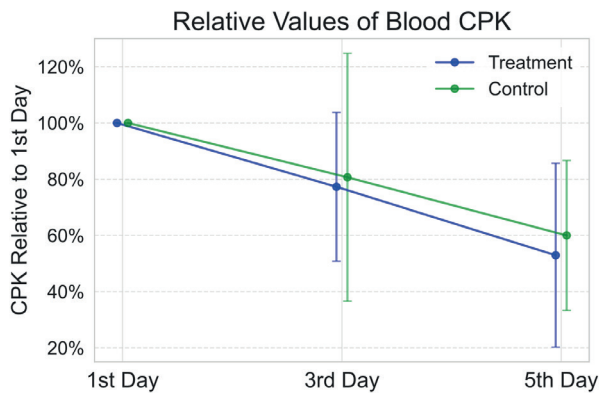


Figure 2. Relative values of CPK serum levels at 1-3-5 days post-operatively

authors (11) found that patient treated through DAA had lower serum CPK levels when compared to those treated through posterior approach. In our experience we tried to investigate the impact of a soft tissue shield on muscles through CPK measurements. Unfortunately, the statistical analysis didn't show any significant difference between the control group and the test group serum CPK levels. However, preliminary data of our study, even if it is conducted with a restricted number of patients, suggest at least partial effectiveness of Alexis Orthopedic Protector in shielding soft tissues from surgical harm due to contact with scalpels, retractors, reamers and broaches. In any case, using the device during hip arthroplasties we found several advantages for the surgical team. In particular, the device reduces the direct contact and pressure of retractors on soft tissues while protecting them especially from broaches and reamers. Furthermore Alexis Orthopaedic Protector shields soft tissues from the porous surface of cementless acetabular cups and femoral stems. This way it allows to introduce through anterior approach also large diameters cups without damaging soft tissues (Figure 3A).

Moreover, it provides elastic traction on muscles allowing a better return of muscle tone at the end of the surgical procedure, making wound closure easier and more precise (Figure 3B). We think that the elastic compression on muscles provides also certain degrees of intramuscular hemostasis, which helps in reducing even more the need of blood transfusions and reduces muscle soreness due to intramuscular hematomas. The

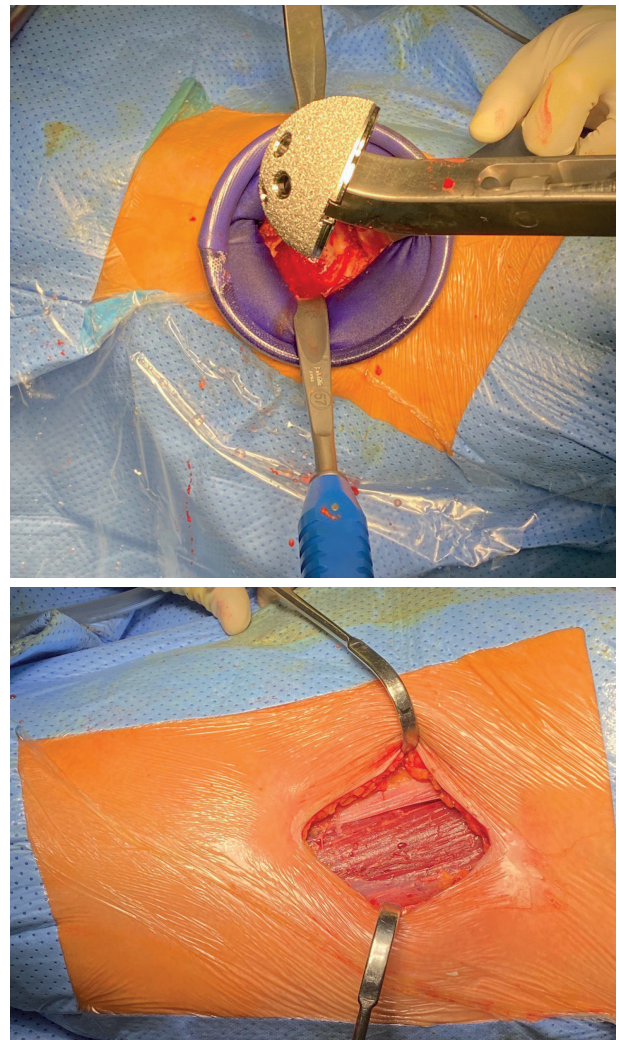


Figure 3. A) Large diameter acetabular cup with porous surface. B) Surgical wound after device removal

reduction of peri-operative bleeding is a key factor in hip surgery as a greater tissue trauma with consequent bleeding results in the need of drainage positioning and maintenance for longer periods, which is a risk factor for heterotopic ossification (12,13)

Giving its waterproof features, it locally maintains a certain degree of moisture on muscles, skin and subcutaneous tissue thus avoiding withering of tissues, which creates an adverse environment for wound healing.

In the end, it enhances visibility for the surgeon focusing the attention on a restricted area of the surgical field, allowing also better cleanliness, debris removal and optimal exposure of joint capsule and of the joint

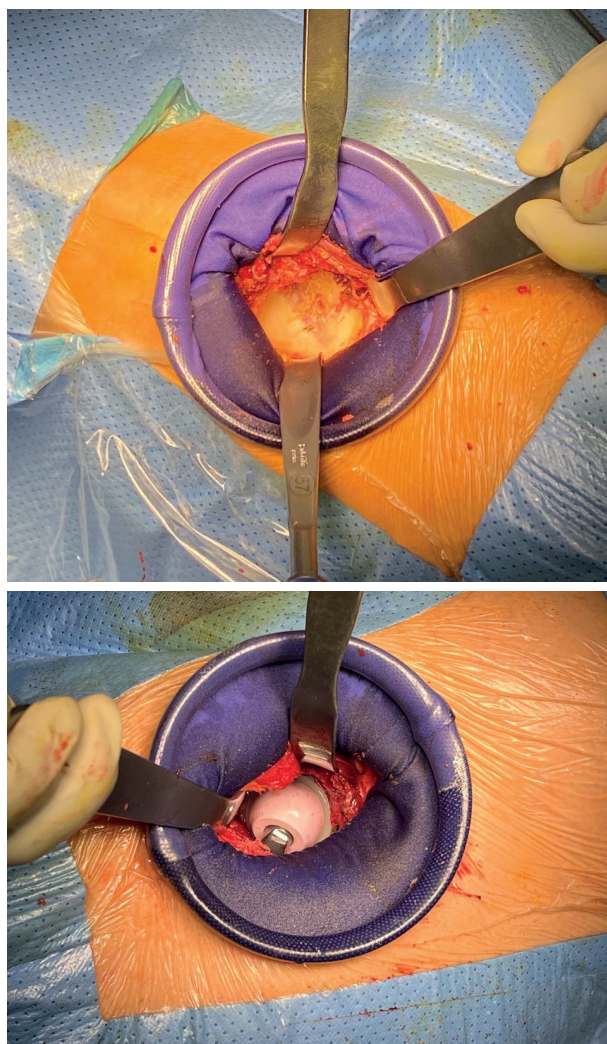


Figure 4. A) Optimal acetabular exposure. B) Good exposure of implant

cavity (Figure 4A-B). This helps also the assistant in keeping the surgical field clean from blood and debris.

The anti-bacterial properties of Alexis device have been studied in non-traumatic colorectal surgery (14,15) and in cesarean section surgery (16) with a significant decrease in wound infection in the Alexis group. This suggests that it may reduce surgical site infection in orthopaedic surgery too, in fact we didn't experience any deep or superficial surgical site infection in the Alexis with group.

Among the disadvantages we report the placement time, that requires around 30-45 seconds in order to appropriately positionate and strain the device.

The limits of our study are for sure the small size of sample and the lack of CPK measurement prior to surgical procedure. In fact, that way we could have evaluated the variation of CPK levels considering as benchmark the pre-operative value instead of the 1st day post-operative value.

Conclusions

We think that the adoption of the Alexis Orthopaedic Protector provides several improvements during hip arthroplasty surgical procedure, especially when the DAA is adopted, because it distributes the traction forces around the surgical field with consequent enhanced visibility. For these reasons we think that it would be a useful tool even during the learning curve of young surgeons. Given all these useful features, we strongly believe that Alexis Orthopaedics device could help also in hip arthroplasties performed through mini-invasive bikini approach.

However, the small number of patients isn't enough to perform an accurate statistical analysis, and in further studies patients should be divided between hip arthroplasties performed after neck fracture and those performed in elective patients.

Conflicts of interest: All authors declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Ethics Approval and Consent to Participate: All procedures were performed following written informed patient consent and in accordance with the ethical standards of the institutional research committee and the 1964 Declaration of Helsinki and its subsequent amendments or comparable ethical standards.

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