Original research article

IJAO

# High rate of infection eradication following cementless one-stage revision hip arthroplasty with an antibacterial hydrogel coating

The International Journal of Artificial Organs I–5 © The Author(s) 2021 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/0391398821995507 journals.sagepub.com/home/jao



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#### Abstract

**Purpose:** We conducted a retrospective study to evaluate the outcomes of one-stage revision total hip arthroplasty (THA) following periprosthetic joint infection (PJI) in terms of eradication of the infection, improvement of pain and joint function. We hypothesized that this treatment strategy could lead to satisfying results in selected patients after preoperative microorganism isolation.

**Methods:** Ten patients underwent cementless one-stage revision hip arthroplasty with antibacterial hydrogel coating for the treatment of an infected THA. Inclusion criteria were: the presence of a known organism with known sensitivity, patients non-immunocompromised with healthy soft tissues with minimal or moderate bone loss. Mean age at surgery was 69.4 years. Assessment included objective examination, Harris hip score, visual analog scale pain score, standard X-rays.

**Results:** At a mean follow-up of 3.1 years (range, 2–5 years), none of the patients had clinical or radiographic signs suggesting recurrent infection. Follow-up examination showed significant improvement of all variables compared to pre-operative values (p < 0.05). Radiographs did not show progressive radiolucent lines or change in the position of the implant.

**Conclusions:** One-stage revision THA with antibacterial hydrogel coated implants represents a safe and effective procedure providing infection eradication and satisfying subjective functional outcomes in selected patients.

#### **Keywords**

Hip, infection, antibacterial hydrogel coating, infected hip arthroplasty, one-stage revision arthroplasty, periprosthetic joint infection, revision hip arthroplasty, outcomes

Date received: 22 June 2020; accepted: 28 January 2021

## Introduction

The incidence of periprosthetic joint infection (PJI) following total hip arthroplasty (THA) is rising due to the increasing number of surgeries being performed, as well as with increasing age and life expectancy, and with the growing number of patients with co-morbidities.<sup>1</sup>

The treatment of this serious complication is debated, although two-stage exchange currently represents the most reliable surgical strategy leading to effective infection eradication. However, it presents several drawbacks, such as extensive bone and soft tissue damage, prolonged hospitalization and high mortality.<sup>2,3</sup>

Due to these limitations, one-stage approach is recently gaining popularity. In fact, this surgical strategy prevents

the need for two major surgical procedures and prolonged antibiotic therapy, when performed in patients after preoperative microorganism isolation.

One-stage exchange using antibiotic-loaded cement has shown promising results with an infection eradication

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| Table | ١. | Patient | demographic | s and | anth | ropometric | data. |
|-------|----|---------|-------------|-------|------|------------|-------|
|-------|----|---------|-------------|-------|------|------------|-------|

| Age at surgery (SD) (year) | 69.4 (SD:8.3) |
|----------------------------|---------------|
| Gender                     |               |
| Male                       | 5             |
| Female                     | 5             |
| Side                       |               |
| Left                       | 4             |
| Right                      | 6             |
| Type of infection          |               |
| Delayed (<2 years)         | 8             |
| Late (>2 years)            | 2             |
|                            |               |

SD: standard deviation.

rate of up to 82 % and with results similar to two-stage procedures.  $^{4\!-\!8}$ 

In addition, satisfying outcome following one-stage exchange with the use of uncemented implants have been reported.<sup>9-11</sup> Recently, a reduced recurrence rate after one-stage exchange combined with the use of defensive anti-bacterial coating (DAC<sup>®</sup>, Novagenit Srl, Mezzolombardo, Italy), has been reported, and DAC<sup>®</sup>-coated implants demonstrated to be safe and effective in the treatment of PJIs requiring revision surgery.<sup>12,13</sup>

We conducted a retrospective study to evaluate the outcomes of one-stage revision THA using DAC<sup>®</sup>-coated implants in terms of eradication of the infection, improvement of pain and joint function. We hypothesized that this treatment strategy could lead to satisfying results in selected patients after preoperative microorganism isolation.

## **Patients and methods**

Between 2014 and 2017, 10 patients treated for an infected hip prosthesis with one-stage revision surgery were retrospectively evaluated.

Inclusion criteria were: patients non immunocompromised with healthy soft tissues with minimal or moderate bone loss, the presence of a known gram positive organism with known sensitivity.

Mean age at presentation was 69.4 years (range, 63– 78 years). Detailed patients' demographic data are reported in Table 1. All surgeries were performed by one single senior surgeon. All investigations were conducted in conformity with ethical principles of research and according to the guidelines expressed by authors' Institution, and informed consent was obtained.

### Surgical technique

First removal of all previously implanted components and cement and meticulous surgical débridement were performed. One stage-exchange with cementless implants was allowed whenever infecting micro-organism and sensitivity were determined before surgery. Intra-operative sampling was performed to confirm pre-operative isolated bacteria. Six hips (60%) were revised with a titanium acetabular components (Pinnacle Multi-Hole Cup with Corail stem (Depuy Johnson & Johnson Co, Warsaw, IN), while Fixa Ti-Por with Recta stem (Adler Ortho, Milan, Italy) was implanted in four patients (40%). In all cases, a hydrogel coating (DAC<sup>®</sup> Novagenit Srl) was used.

The DAC<sup>®</sup> hydrogel was prepared intra-operatively according to the indications reported by the manufacturer. A syringe prefilled with 300 mg of sterile DAC<sup>®</sup> powder was mixed with a solution of 5 mL of sterile water with tailored antibiotics selected according to pre-operative culture, at a concentration ranging from 25 to 50 mg/mL. In all patients, the DAC<sup>®</sup> hydrogel was loaded with a combination of vancomycin 5% and gentamicin 5%. Its application took place immediately before the positioning of the implant components, by directly spreading it on all implant surfaces.

#### Post-operative rehabilitation

In all patients, antibiotic therapy was carried out for 6–8 weeks, starting with a broad spectrum coverage with Vancomycin 1g two times a day and Ciprofloxacin 400 mg two times a day. At discharge, intravenous therapy was converted to targeted oral therapy according to specific microorganism isolation. After surgery, patients started performing passive motion exercises, walking with partial weight-bearing. At 12 weeks postoperatively, patients were allowed to resume activity without restriction.

#### Outcome measures

Clinical outcomes were evaluated pre-operatively and at the most recent follow-up and included clinical and radiographic signs of infection eradication, range of motion, Harris Hip Score (HHS), visual analog scale (VAS) pain score. Standard X-rays were examined for signs of loosening, osteolysis, and modifications in implant position.

#### Statistical analysis

Data were analyzed using the program IBM SPSS Statistics for Windows<sup>®</sup>, Version 21.0 (IBM Corp., Armonk, NY). Paired *t*-test (two sided test and  $\alpha$ =0.05) was utilized to compare preoperative and follow-up status. Differences with a *p* value < 0.05 were considered statistically significant.

## Results

After a mean follow-up of 3.1 years (range, 2–5 years), none of the 10 patients had clinical or radiographic signs suggesting recurrent infection.

Both functional and pain scores significantly improved. Detailed overall clinical outcomes are reported in Table 2.

| Table 2. C | Overview | of the | results o  | of cl | linical | assessmen | t |
|------------|----------|--------|------------|-------|---------|-----------|---|
|            |          | or the | i esuits c |       | mincai  | assessmen | L |

|                             | Pre-operative   | Post-operative | þ Value |  |
|-----------------------------|-----------------|----------------|---------|--|
| Harris hip score (mean, SD) | 38.1 (SD: 10.3) | 81.3 (SD: 6.7) | p<0.001 |  |
| VAS pain score (mean, SD)   | 6.8 (SD: 3.2)   | 1.9 (SD: 2.4)  | þ<0.001 |  |

VAS: visual analog scale; SD: standard deviation.

Table 3. Epidemiology of infecting organisms.

| Pathogen                             | Number (%)                 |  |  |
|--------------------------------------|----------------------------|--|--|
| CNS<br>MRSA<br>Staphylococcus aureus | 5 (50)<br>4 (40)<br>1 (10) |  |  |
|                                      |                            |  |  |

MRSA: methicillin-resistant Staphylococcus aureus; CNS: coagulasenegative Staphylococci.

The mean HHS improved from an average pre-operative value of 38.1 (SD: 10.3) points to 81.3 (SD: 6.7) points (p < 0.001). VAS improved from 6.8 (SD: 3.2) to 1.9 (SD: 2.4) (p < 0.001). Standard radiographs did not show progressive radiolucent lines or signs of mechanical loosening of the components. Bacteria were isolated in all patients, most of them being coagulase-negative *Staphylococci* (CNS) and methicillin-resistant *Staphylococcus aureus* (MRSA) (Table 3).

## Discussion

The most important finding of the present study was that none of the subjects had clinical or radiographic signs suggesting recurrent infection, following one-stage exchange arthroplasty using cementless implant and a hydrogel coating. Most patients reported subjective and objective satisfying outcomes at an average follow-up of 3.1 years.

PJI is a relatively frequent and serious complication following prosthetic joint implantation, which can be devastating and life changing, with significant psychosocial and socioeconomic costs.<sup>14</sup> For this reason, the orthopedic community is putting a lot of effort in developing appropriate treatment strategies.<sup>15–17</sup>

Advantages of one-stage revision surgery include the fact that patients undergo a single major procedure, thus avoiding complications associated with the use of temporary spacers such as spacer dislocation or allergic reactions to the antibiotics, reducing hospitalization times and costs.

A main requirement for one-stage exchange arthroplasty is that the infecting organism and its sensitivity must be determined before surgery.<sup>18,19</sup>

Currently several surgeons support the use of one-stage revision with cement alone or cementless prostheses together with bone grafts.<sup>20–22</sup> Winkler et al.<sup>22</sup> reported satisfying results with a 92% eradication of infection in 34 hips affected by PJI after an average time of 2 years after surgery.

Recently, antibacterial coatings have been proposed as an adjunct in the treatment of PJIs, either combined to oneor two-stage revision procedures.<sup>12,23–27</sup> The success of these procedures relies in the use of a coating technology preventing biofilm formation and implant-related infection.<sup>24</sup> Zagra et al.<sup>23</sup> showed that the use of an antibacterial hydrogel coating was effective in reducing hospitalization time when combined to cementless two-stage THA.

Similarly, Capuano et al.,<sup>12</sup> in a comparative study on 44 patients, reported similar results between patients with PJI treated with one-stage exchange with antibacterial hydrogel coated implants and patients undergoing two-stage revision, without the coating.

The excellent infection eradication rate of 100% reported in our case series may be due to highly selective criteria for patient selection. For patient not fulfilling criteria, a twostage procedure was planned. In fact, it has to be clear that its use is limited to non-immunocompromised patients with identified gram-positive microorganisms, absence of sinus tract and acceptable soft tissue coverage. Most commonly isolated bacteria in our case series were CNS and MRSA, which are most frequently causative agents of PJIs as previously reported.<sup>28,29</sup> The relatively high rate of MRSA can be related to the small sample size; it has to be noted that MRSA screening is not routinely performed at our Institution. Institutional prescreening programs for the detection and eradication of MRSA among patients undergoing joint replacement surgery may reduce postoperative rates of PJIs,<sup>30</sup> although the optimal approach to S. aureus screening and decolonization remains uncertain.31,32

Still no evidence-based criteria for the management of PJIs exist for one-stage revision surgery, and the efficacy of antibacterial hydrogel coatings has yet to be substantiated with further randomized clinical trials with longer follow-ups.

Limitations of the present study include its retrospective nature, the relatively small sample size and the absence of control group. The limited number of patients is due to the fact that this is an unfrequent complications, and these approaches requires adopting highly selective indications as criteria for patient selection.

## Conclusion

One-stage revision THA with antibacterial hydrogel coated implants represent a safe and effective procedure providing infection eradication and satisfying subjective functional outcomes in patients with infected knee arthroplasty. In order to succeed it should be performed in non-immunocompromised patients with healthy soft tissues with minimal or moderate bone loss and the infecting organism and its sensitivity must be determined before surgery.

#### **Declaration of conflicting interests**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Each author discloses any financial and personal relationships (e.g., employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, grants or other funding) that might pose a conflict of interest in connection with the submitted article.

#### Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study was funded by the Italian Ministry of Health.

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