ORIGINAL ARTICLE

Single use instruments for total knee arthroplasty

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ABSTRACT

Aim Total knee arthroplasty represents a procedure that is successfully performed to relieve functional limitation and pain in advanced stages of osteoarthritis. In the next 20 years the number of these procedures will be increased about four times. Patient specific instrumentation (PSI) has been introduced in the past years. The aim of this study was to evaluate whether SUI are more useful in clinical, organizational and economic terms.

Methods A database search about single use instrumentation (SUI) was conducted on PubMed and Google Scholar for the period 2010-2020 using the following key "total knee replacement", "total knee arthroplasty", "single use instruments", and "disposable instruments". The results of the selected studies were classified according to clinical, economic and organizational criteria.

Results The main advantage of SUI has been reported to reduce costs, timely turnover of operating rooms, maximizing the operating room utilization and patient throughput, improving the number of outpatient total joint replacements. No difference has been found other than with regard to conventional instruments in terms of clinical outcome such as hip-knee-ankle angle and other radiographic parameters, Oxford Knee Score, while a decreased infection rate has been demonstrated. Regarding the economic aspect, a reduction of direct and indirect reduction of costs has been shown for the cost of instruments reprocessing, tray sterilization, 90-day infection rate.

Conclusion The SUI can be an alternative to conventional instruments, but there are still few studies in the literature regarding clinical outcomes.

Keywords: joint replacement, prosthesis, osteoarthrosis

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INTRODUCTION

Total knee arthroplasty (TKA) represents a procedure that is successfully performed to relieve functional limitation and pain in advanced stages of osteoarthritis (1). In 2009, 686,000 total knee prostheses were performed in the USA alone; a recent study predicted that in 2040 there will be a 401% increase in the number of procedures performed (1). Usually, the instruments used for knee replacement surgery are reusable and are sterilized and packaged (1). The number of trays used for each traditional individual procedure is between 6 and 8: this could increase the possibility of contamination of the surgical instruments (2). In the past years the instrumentation for knee replacement surgery has undergone innovations with the introduction of the patient specific instrumentation (PSI) (1). Using specific MRI of CT knee scans, cutting masks specific to the patient's knee anatomy are produced, and used as cutting jigs during knee replacement surgery (1). Several advantages have been advocated using PSI technology, such as reduced surgical time, no violation of the intramedullary canal, decreased blood loss and decreased in the instrumentation trays optimizing the operative room time (3). Recently, on the basis of PSI clinical results and following a progressive improvement of the manufacturing process of cutting guides, Single Use Instrumentation (SUI) has been introduced and proposed as a method to increase the sterility rate of the instruments (2), reducing post-operative knee infection risk. It consists of plastic-disposable instruments that faithfully replicate metallic instrumentation used during knee replacement surgery: two or three sterile packs which include femoral and tibial guides, rods, and jigs (2). The main advantage of this technology has been reported to reduce costs, the timely turnover of operating rooms, maximizing the operating room utilization and patient throughput, improving the number of outpatient total joint replacements (4).

The aim of this article was to evaluate whether SUI are more useful in clinical, organizational and economic terms.

MATERIALS AND METHODS

A database search about single use instrumentation (SUI) on PubMed and Google Scholar was conducted to look for articles in English for the period 2010-2020 using the following key words: total knee replacement, total knee arthroplasty, single use instruments, and disposable instruments. The results of the selected studies were classified according to clinical, economic and organizational criteria. Clinical criteria were focused on hospital clinical, functional and radiological data. For the organizational data, the operating room times have been considered.

RESULTS AND DISCUSSION

Clinical aspects

Concerning the use of SUI, controversy still exists concerning the use of this technology improving clinical outcomes after TKA (5-7). This depends on the lack of mild and long-term results available that describe clinical outcomes, cost- effectiveness and revision rates (Table 1). Abane et al. (5) evaluated 210 performed TKAs using different types of instruments: conventional (CI), patient-specific cutting guides (PSI) and single use and patient- specific cutting guides (SUI) groups. The use of a SUI in TKA provided similar results to those obtained with traditional PSI and CI: no difference was found in terms of clinical results, operative time, number of unit transfusion and length of hospital stay (5). The mean hip-knee-ankle angle was significantly lower for the SUI group when compared to the CI group, indicating an overall varus alignment of the lower limb with the SUI instrumentation. Similar findings were observed for femoral and tibial components positioning. In addition, patient-specific guides both traditional and single-use (PSI and SUI) showed significant trend towards varus placement of the tibial component (5). Attard et al. (6), in a randomized controlled trial, allocated the patients into four separate groups by block stratification. The four instrument groups were: conventional/reusable (CVR), patient-specific/reusable (PSR), conventional/single-use (CVS) and patient-specific/single-use (PSS) instrumentation. Clinically, at 6 weeks post operatively, in terms of Oxford Knee Score, the best result was achieved by the PSR group. Meanwhile at 1-year follow up the best score was achieved by the CVR group: this score was significantly greater than the one reported in the PSR group. The lowest average score at 1 year was reported in the CVS group, but not statistically different if compared with the CVR group (6). A recent prospective, non-randomized multi-centre clinical study (7) was conducted on 2 separate in-

Table 1. Evidence on the use of single use instruments (SUI) for total knee arthroplasty (TKA) compared with other instruments

Author (reference number)	Aim of the study	Outcomes	Economic analysis	Organizational aspects
Abane et al. (5)	Comparison between CI, PSI and SUI	No significant differences in terms of clinical results, operative time, number of unit transfusion and length of hospital stay; Hip-knee-ankle angle was significantly lower for the SUI group compared to the CI group	N/A	Operative time was not reduced in both patient-specific groups when compared to CI
Attard et al. (6)	Comparison between CVR, PSR, CVS, SUI	At 6 weeks post-operatively the best OKS result was achieved by PSR group; At 1-year follow up the best OKS was achieved by the CVR group and lowest average score was reported in the CVS group	The cost for surgery was cheaper in SUI procedures CI (-24,6%, £ 320 vs £ 424,12)	SUI instrument took longer to set up the operating room than the CI instrumentation; All variables recorded after the set-up of the instruments were quicker with the SUI and were significantly shorter with SUI
Bugbee et al. (7)	Comparison between 2 CI and SUI	No significant differences between SU and CI in most radiographic parameters; Post-operative adverse events in 5 CI subjects and in 3 SUI subjects	N/A	Using SUI than CI the OR set up time was decreased by 30%, while other times such as surgical, OR clean down, and total OR were similar
Siegel et al. (8)	Comparison of rate of surgical site infection between CI and SUI	Lower infection rate seen in SUI group (0.2%) than in CI group (3%)	The time and equipment cost savings from using SUI amounted to between $480 and $600 per case	Instrument set-up time and instrument clean-up time were decreased using SUI; Central supply clean-up time was decreased by 60 minutes using SUI; There was no change in operative time
Mont et al. (14)	Comparison of time parameters between CI and SUI	N/A	N/A	Time parameters were significantly shorter with the SUI: they calculated a potential total reduction of 17.1 minutes per case
Goldberg et al. (15)	Comparison of perioperative complication and economic differences between: CI and SUI	No significant differences in terms of major perioperative complications including re-admission, infection, reoperation and revision	Potential economic benefit is $1198 per TKA procedure, comparing the SUI to the CI	Decrease of the operating room turnaround time with SUI; Reduction of the logistical burden of loaner instrumentation with SUI

CI, conventional instrument; PSI, patient-specific cutting guides; SUI, single use and patient-specific cutting guides; CVR, conventional/reusable; PSR, patient-specific/reusable; CVS, conventional/single-use; PSS, patient-specific/single-use instrumentation; OKS, Oxford Knee Score; OR, operative room

strument systems, one reusable instrument and the other SUI, both designed for implanting the Attune Knee System (De Puy Synthes Joint Reconstruction, Warsaw, USA). Seventy-five subjects completed the study (41 SUI/34 reusable instrument). No significant difference was found between SUIs and reusable instruments (RUI) in most radiographic parameters (distal femoral varus-valgus, proximal tibial varus-valgus, tibial slope, or subjects within 3° of target). There were six post-operative adverse events in five reusable instrumentation subjects and three post-operative adverse events in the SUI group (7).

Siegel et al. (8) compared the rate of surgical site infection between two groups (SUI and Reusable instrument). A total of five patients in the reusable instrument group (3%) underwent revision surgery for infection, whereas only 1 patient in the SUI cohort (0.2%) required a revision surgery (p=0.006). They concluded that the decreased infection rate seen in the study is most likely due to enhanced maintenance of sterility and decreased risk of contamination when using single use instruments (8). This result is in contrast with those of Goldberg et al. (9), which did not find statistically significant differences in terms of major perioperative complications including re-admission, infection, reoperation and revision, between the single use instruments or traditional reusable instrument groups.

Organizational aspects

By 2026, more than a half (51%) of all total joint replacements will occur in the outpatient setting (vs 49% inpatients) (10). Several studies have focused on the turnover in operating room (OR) for optimizing the time thus to increase the number of cases a day (10). Bert et al. (4) in their paper have concluded that the ability to reduce costs, timely turnover of operating rooms to maximize operating room utilization and patient throughput could improve the number of outpatient total joint

replacements. Cendan and Good (11) concluded that with a reduction of turnover time from 15 to 20 minutes 3 or 4 times a day, 1 more surgery could be performed. On the other hand, Dexter et al. (12) have highlighted that reducing the turnover time is generally only important when multiple operations of short duration are anticipated. Furthermore, an excessive number of tray instruments may also cause operative delays by the surgical technician spending extra time setting up the instruments, finding the correct instrument on a cluttered tray, or handing the surgeon an incorrect instrument due to clutter (13). However, Attard et al. (6) found that the SUI, used in conventional procedures, took longer to set up the operating room than the conventional reusable instrumentation. Conversely, all variables which were recorded after the set-up of the instruments were quicker with the SUI and were statistically significantly shorter when the SUI was used (6). Similarly, in their study Mont et al. (14) observed that time parameters were significantly shorter with the SUI when compared to the conventional instrumentation for most of the operating room parameters evaluated (navigated and non-navigated cases). In the best scenario, if single use instruments were used, they calculated a potential total reduction of 17.1 minutes per case: 9-minute savings in instrument set-up time, a 1.2-minute savings in procedure time, and a 6.9-minute savings in instrument clean-up time (14).

A similar result was found by another study (8): in a single-use cohort, instrument set-up time was decreased by 15 minutes and instrument clean-up time was decreased by 14 minutes ($p<0.05$). The central supply clean-up time was decreased by 60 minutes ($p<0.05$). There was no change in operative time. Similar results were found by Bungbee et al. (7): using the SUIs rather than reusable instruments, the OR set up time was decreased by 30%, while other times such as surgical, OR clean down, and total OR were similar.

Economic analysis

An economic analysis has been studied by many authors (2,6,8,15). The main question about the single use instruments is if there is a direct and indirect reduction of costs of a case.

In a paper made by Bonutti et al. (2), the cost of instruments reprocessing was estimated to be lower by between $140 and $220 per set, as a result of the smaller number of trays. The time savings for rewrapping trays was shorter, for each instrument case, the saving was between $75 and $330. On the other hand, the cost of disposable cutting blocks is higher than conventional instruments. In addition, it could be necessary to open multiple sets of instruments, for example in case of an intraoperative femoral sizing change (2).

Attard et al. (6) in their analysis found that the cost for surgery was cheaper in SUI procedures than in conventional/reusable procedures (-24.6%; £ 320 vs £ 424.12).

A Goldberg study (15) was focused to investigate a range of potential costs savings for TKA procedures performed with single use instruments. Four variables related to TKA costs and logistics were considered in this study: turnover time, tray sterilization, tray management time, and 90-day infection rates. They simulated 200 sites: in 95% of cases, at least $500 per case and in 48% of cases at least $1000 were saved (15).

Siegel et al. (8) have calculated a saving per surgery, with single use instrumentation, when compared with traditional use in this way: OR man-hours decreased by $55.50, central supply man-hours decreased by $50.36, supply and sterile rewrapping costs decreased by $375.00 per 5 traditional trays. The cost of the SUI set was quoted at $490. They concluded stating that the time and equipment cost savings from using single-use equipment for total knee arthroplasties amounted to between $480 and $600 per case (8).

The incidence of periprosthetic infections is around 1-2%, but considering the increase in the number of cases per year, the number of revision surgeries is expected to grow (16).

Periprosthetic infections remain a challenge as well as a problem in prosthetic surgery. A study showed that the cost of a periprosthetic infection procedure is roughly $ 116,000, which is approximately 5 times higher than the cost of a primary implant (17). Surgical site infections (SSIs) are the most common (25.2%) indication for revision total knee arthroplasty (TKA) and it is the most common reason for revision surgery such as arthrotomy and prosthesis components removal (79.1%) (18). The SSIs impose a higher cost for the prolonged hospital stay or hospital readmission. A study observed a correlation between SSIs and post-sterilization contamination of sets containing surgi-

cal instruments (19). Further, it was observed that the current method of checking and maintaining sterility in the OR is inadequate (20). In addition, a study (21) has shown that even a wrap defect of 1.1 mm could allow bacterial contamination. In conclusion, single use instruments can be an alternative to conventional instruments. Many studies agree in stating that there is an economic saving and a reduction in the operating room turn over times. On the other hand, there are still few studies in the literature regarding clinical outcomes.

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TRANSPARENCY DECLARATION

Conflict of interest: None to declare.

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